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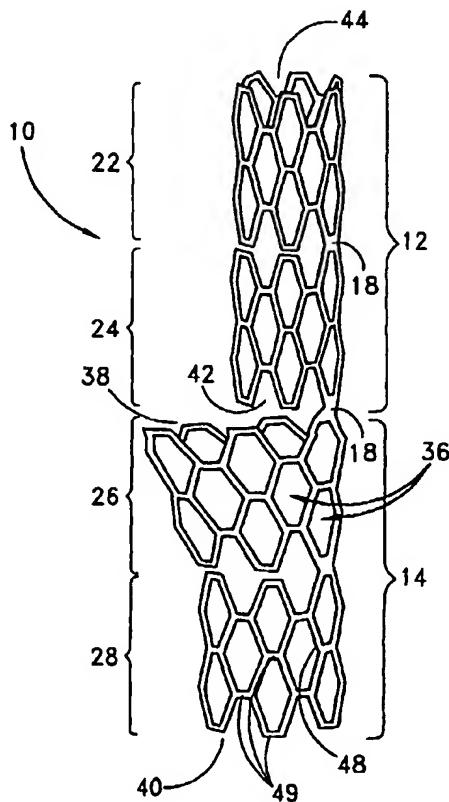
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(54) Title: ENDOPROSTHESIS DEPLOYMENT SYSTEM FOR TREATING VASCULAR BIFURCATIONS



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(57) Abstract: A device is configured for treating pathological narrowing of fluid-carrying conduits of the human body (such as blood vessels) in an area of a bifurcation (30). In particular, a stent delivery system (100) configured to carry one or more of a pair of dissimilar stents (12, 14). At least one of the stents (12, 14) is particularly suited for treating a widened portion of a blood vessel (46) immediately proximal to a bifurcation (30). The stent delivery system (100) can also include a handpiece (140) adapted to selectively deliver the stents.



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ENDOPROSTHESIS DEPLOYMENT SYSTEM FOR TREATING VASCULAR BIFURCATIONS

Background

5 Scope of the Invention

The present invention relates to an apparatus permitting the treatment of bodily conduits, typically blood vessels, in an area of a bifurcation, e.g. in an area where a principal conduit separates into two secondary conduits. It also relates to equipment for positioning this apparatus.

10 Description of the Related Art

It is known to treat narrowing of a rectilinear blood vessel by means of a radially expandable tubular device, commonly referred to as a stent. This stent is introduced in the unexpanded state into the internal lumen of the vessel, in particular by the percutaneous route, as far as the area of narrowing. Once in place, the stent is expanded in such a way as 15 to support the vessel wall and thus re-establish the appropriate cross section of the vessel.

Stent devices can be made of a non-elastic material, in which case the stent is expanded by an inflatable balloon on which it is engaged. Alternatively, the stent can be self-expanding, e.g. made of an elastic material. A self-expanding stent typically expands spontaneously when withdrawn from a sheath which holds it in a contracted state.

20 For example, United States Patent Nos. 4,733,065 and 4,806,062 illustrate existing stent devices and corresponding positioning techniques.

A conventional stent is not entirely suitable for the treatment of a narrowing situated in the area of a bifurcation, since its engagement both in the principal conduit and in one of the secondary conduits can cause immediate or delayed occlusion of the other secondary 25 conduit.

It is known to reinforce a vascular bifurcation by means of a stent comprising first 30 and second elements, each formed by helical winding of a metal filament. The first of the two elements has a first part having a diameter corresponding to the diameter of the principal vessel, and a second part having a diameter corresponding to the diameter of a first one of the secondary vessels. The first element is intended to be engaged in the principal vessel and the second element is intended to be engaged in the first secondary vessel. The second element has a diameter corresponding to the diameter of the second

secondary vessel. After the first element has been put into place, the second element is then coupled to the first element by engaging one or more of its turns in the turns of the first element.

5 This equipment permits reinforcement of the bifurcation but appears unsuitable for treating a vascular narrowing or an occlusive lesion, in view of its structure and of the low possibility of radial expansion of its two constituent elements.

Moreover, the shape of the first element does not correspond to the shape of a bifurcation, which has a widened transitional zone between the end of the principal vessel and the ends of the secondary vessels. Thus, this equipment does not make it possible to
10 fully support this wall or to treat a dissection in the area of this wall. Additionally, the separate positioning of these two elements is quite difficult.

Summary of the Invention

There is provided in accordance with one aspect of the present invention, a method of treating a vascular bifurcation of a main vessel into a first and a second branch vessels.
15 The method comprises the steps of providing a delivery catheter having a stent thereon, the stent having a proximal end and a distal end and being self expandable to a configuration in which the proximal end has a smaller diameter than the distal end. The catheter is positioned such that the stent is at a treatment site within the main vessel, with the distal end adjacent the bifurcation. The stent is deployed in the main vessel such that the distal end communicates with both the first and the second branch vessels.
20

In one implementation of the invention, the method additionally comprises the step of dilating the treatment site prior to the positioning step. The deploying step may comprise removing a restraint from the stent and permitting the stent to self expand. The method may additionally comprise the step of deploying a second stent in one of the first and second branch vessels.
25

In one implementation of the invention, the distal end of the stent expands to a diameter that is at least about 105% of the diameter of the proximal end of the stent. In certain applications, the distal end of the stent expands to a diameter that is at least about 110% of the diameter of the proximal end of the stent.

30 In accordance with another aspect of the present invention, there is provided a deployment system for treating a bifurcation of a main vessel into a first and second branch vessels. The deployment system comprises an elongate flexible body, having a proximal

end and a distal end. A tapered stent is carried by the distal end of the body. A releasable restraint for restraining the stent is also carried by the body. The distal end of the stent is larger in diameter than the proximal end of the stent in an unconstrained expanded configuration.

5 The deployment system may additionally comprise a guidewire lumen extending axially through at least a portion of the flexible body. The guidewire lumen has a proximal access port and a distal access port. In one implementation, the proximal access port is positioned along the flexible body, spaced distally apart from the proximal end. In another implementation, the proximal access port is positioned at the proximal end of the body.

10 The releasable restraint may comprise an axially moveable control element extending along the length of the flexible body. The releasable restraint may also comprise a tubular sheath, for restraining the stent. The tubular sheath may be attached to an axially moveable pull wire.

15 In accordance with a further aspect of the present invention, there is provided a method of treating a vascular bifurcation of a main vessel into first and second branch vessels. The method comprises the steps of deploying a substantially cylindrical stent in a first branch vessel which is distal to the bifurcation, and deploying a tapered stent in the main vessel, proximal to the bifurcation. The tapered stent tapers in a distal direction from a smaller proximal diameter to a larger distal diameter which faces the bifurcation.

20 In accordance with another aspect of the present invention, there is provided a stent deployment catheter. The catheter comprises an elongate flexible tubular body, having a proximal end and a distal end. A noncylindrical, self expandable stent is carried by the distal end. A hand piece is provided on the proximal end. A control is provided on the hand piece, for controllably removing a restraint from the noncylindrical self expandable stent. In one application, the control has a first position for indicating a partial deployment of the stent, and a second position indicating complete deployment of the stent.

25 All of these embodiments are intended to be within the scope of the present invention herein disclosed. These and other embodiments of the present invention will become readily apparent to those skilled in the art from the following detailed description of the preferred embodiments having reference to the attached figures, the invention not being limited to any particular embodiment(s) disclosed.

Brief Description of the Drawings

Having thus summarized the general nature of the invention, certain preferred embodiments and modifications thereof will become apparent to those skilled in the art from the detailed description herein having reference to the attached figures, of which:

5 Figure 1 is a side view of a first embodiment of a stent system shown in an expanded state;

Figure 2 is a perspective, partial cutaway view of the stent system of Figure 1 shown in a state of radial contraction, as disposed on a delivery catheter;

10 Figure 3 is a longitudinal sectional view of a bifurcation treatable by the stent system of Figure 1;

Figure 4 is a section view of the bifurcation of Figure 3 showing a delivery catheter positioned therein;

15 Figure 5 is a section view of the bifurcation of Figure 3 showing an embodiment of a stent system shown in a partially contracted state on a portion of a delivery catheter;

Figure 6 is a section view of the bifurcation of Figure 3 showing an embodiment of a stent system shown in an expanded and fully deployed state;

Figure 7 is a section view of a bifurcation presenting an aneurysm and an embodiment of a stent system shown deployed therein,

20 Figure 8 is a side view of a stent system according to a second embodiment shown in an expanded state;

Figure 9 is a plan view of a delivery catheter usable to deploy a stent system having certain features and advantages;

Figure 9A is an alternative embodiment of a proximal handpiece of the delivery catheter of Figure 9;

25 Figure 9B is an alternative embodiment of the delivery catheter of Figure 9;

Figure 9C is a section view of a portion of the delivery catheter of Figure 9 taken through line 9C-9C and specifically showing an alternative pull wire lumen;

Figure 9D is a section view of a portion of the delivery catheter of Figure 9 taken through line 9D-9D and specifically showing a retaining band;

30 Figure 9E is a detail view of a retraction band retention assembly of the delivery catheter of Figure 9;

Figure 10 is a partial cutaway view of a distal portion of the catheter of Figure 9 including a stent system disposed thereon;

Figure 10A is an alternative embodiment of a distal end assembly of the delivery catheter of Figure 9B;

5 Figure 10B is a detail view of a distal portion of the outer sheath shown in Figure 10;

Figure 10C is a section view taken along the line 10C-10C of Figure 10;

Figure 11A is a plan view of a transitional portion of the catheter of Figure 9;

10 Figure 11B is a cross sectional view of the transitional portion taken along the line 11B-11B of Figure 11A;

Figure 11C is a transverse sectional view of the transitional portion taken along the line 11C-11C of Figure 11A;

15 Figure 11D is a cross sectional view of the proximal shaft taken along the line 11D-11D of Figure 11A;

Figure 12 is a side section view of a distal portion of an embodiment of a delivery catheter having certain features and advantages;

Figure 13 is a section view of a bifurcation showing an embodiment of a delivery catheter positioned therein;

20 Figure 14 is a section view of a bifurcation showing a first stent in a partially deployed state;

Figure 15 is a section view of a bifurcation showing a first stent in a fully deployed state;

25 Figure 16 is a section view of a bifurcation showing a second stent in a partially deployed state;

Figure 17 is a section view of a bifurcation showing a second stent in a fully deployed state;

Figure 18 is a section view of a bifurcation as in Figure 17, with a second branch stent deployed in the second branch;

30 Figure 19 is a schematic elevation view of a single-stent delivery system for delivering a cylindrical stent;

Figure 20 is a schematic elevation view of the single-stent delivery system of Figure 19 showing the sheath in a proximal detail view;

Figure 21 is a schematic elevation view of a single-stent delivery system for delivering a conical stent; and

5 Figure 22 is a schematic elevation view of the single-stent delivery system of Figure 21 showing the sheath in a proximal detail view.

Detailed Description of the Preferred Embodiment

As described above, the attached Figures illustrate a stent system and corresponding delivery system for use in treating vessels (e.g. conduits) within the human body at areas of bifurcations. Figure 3 shows a bifurcation 30 in which a main conduit or vessel 32 separates into two secondary branch conduits or vessels 34. The stent system generally includes a pair of dissimilar stents specifically designed for use in an area of a bifurcation 30. Such dissimilar stents are then disposed on an elongate catheter for insertion into the human body. The dissimilar stents may be self-expanding or manually expandable such as 15 by a balloon about which the stents may be disposed as will be described in further detail below.

Figure 1 shows one embodiment of an expandable stent system 10 permitting the treatment of bodily conduits in the area of a bifurcation such as that shown. The stent system 10, shown in an expanded state in Figure 1, generally comprises first 12 and second 20 14 stent portions which may each be divided into two segments, thus creating four successive segments 22, 24, 26, 28, of meshwork structure. The first stent 12 is generally adapted to be disposed in a branch conduit or vessel 34 of a bifurcation, while the second stent 14 is generally adapted to be disposed in a main vessel 32. If desired, the segments may be connected to one another via one or more bridges of material 18. The stents 12, 14 25 are generally movable between a contracted position and an expanded position. As will be clear to those skilled in the art, the stents may be self-expanding or balloon-expandable.

According to the illustrated embodiment, the stents 12, 14 generally comprise an expandable mesh structure which includes a plurality of mesh cells 36. The mesh cells 36 of these segments are in one embodiment elongated in the longitudinal direction of the 30 stents 12, 14 and have in each case a substantially hexagonal shape in the embodiment shown. Those skilled in the art will recognize that the mesh used to form the stent segments 22, 24, 26, and 28 may comprise a variety of other shapes known to be suitable

for use in stents. For example a suitable stent may comprise mesh with repeating quadrilateral shapes, octagonal shapes, a series of curvatures, or any variety of shapes such that the stent is expandable to substantially hold a vessel or conduit at an enlarged inner diameter.

5 The first stent 12 may be divided into two segments 22 and 24 which may be identical to each other and typically have a tubular shape with a diameter which is substantially greater than the diameter of one of the secondary branch conduits 34. Those skilled in the art will recognize that the first stent may comprise a variety of shapes such that it functions as described herein. The first stent 12 may be expandable to a substantially 10 cylindrical shape having a constant diameter along its length. The first stent 12 may comprise a range of lengths depending on the specific desired location of placement. For example, the length of the first stent 12 will typically be between about 1 and about 4 centimeters as desired.

15 The second stent 14 is preferably adapted to be deployed in close proximity to the first stent 12, and may also be divided into upper 26 and lower 28 segments. The lower segment 28 of the second stent 14 typically has a tubular cross-sectional shape and has an expanded diameter which is substantially greater than the diameter of the principal conduit 32 (Figure 3). The upper segment 26 of the second stent 14 preferably comprises a larger 20 diameter at its distal (upper) end 38 than at its proximal (lower) end 40. In one embodiment the upper segment of the second stent portion comprises a substantially conical shape. In an alternative embodiment, the second stent 14 may be tapered radially outward along its entire length in the distal direction. In either embodiment however, the expanded diameter of the distal end 38 of the second stent 14 is preferably substantially larger than the expanded diameter of the proximal end 42 of the first stent 12. For example, 25 the distal end 38 of the second stent 14 may expand to a diameter that is at least about 105%, and preferably at least about 110%, and in some embodiments as much as 120% or more, of the diameter of the proximal end 42 of the first stent 12. The second stent 14 may comprise a range of lengths depending on the specific desired location of placement. For example, the second stent 14 will typically be between 1 and 4 centimeters as desired.

30 In its expanded state, as shown in Figure 1, the upper segment 26 of the second stent 14 typically has mesh cells 36 whose width increases progressively, compared to that of the meshes of the lower segment 28, on the one hand in the longitudinal sense of the dual stent

device 10, in the direction of the distal end 38 of the second stent 14, and, on the other hand, in the transverse sense of the second stent 14, in the direction of a generatrix diametrically opposite that located in the continuation of the bridge 18. Alternatively stated, the upper segment 26 of the second stent 14 preferably comprises a mesh with 5 multiple cellular shapes 36 which may have larger dimensions at a distal end 38 of the stent 14 than those at the proximal end 40 such that the second stent 14 expands to a substantially funnel shape.

In the embodiment shown, this increase in the width of the mesh cells 36 results from an increase in the length of the edges 48 of the mesh cells 36 disposed longitudinally, 10 as well as an increase in the angle formed between two facing edges 48.

This segment 26 thus may have a truncated shape with an axis which is oblique in relation to the longitudinal axis of the first stent 12 when expanded. This shape, for example, corresponds to the shape of the bifurcation shown in the area of the widened transitional zone 46 (Figure 3) which separates the end of the principal conduit 32 from the 15 ends of the secondary conduits 34. In a preferred embodiment, the second stent 14 is placed in close proximity to the first stent 12. For example, the distal end 38 of the second stent 14 is preferably placed within a distance of about 4 mm of the distal end 42 of the first stent 12, more preferably this distance is less than about 2 mm, and most preferably the stents are placed within 1 mm of one another.

20 In the embodiment shown in Figure 1, the distance between first and second stents 12, 14 is held substantially fixed by the provision of a bridge 18 between them. Bridges 18 may be provided to join the first and second stents 12, 14 to one another and/or to join the upper and lower segments 22, 24 and 26, 28 of each stent 12 and 14 together. If present, the bridges 18 may connect the adjacent ends of the segments 22, 24 and 26, 28 and 25 typically have a small width, so that they can undergo a certain flexion, making it possible to orient these segments in relation to one another, in particular the lower segment 24 of the first stent 12 in relation to the upper segment 26 of the second stent 14.

In addition, in other embodiments, the bridges 18 could be integral with one of the 30 connected segments and separately connected, such as by welding, to the other connected segment. For example, the bridge 18 which connects the first and second stents 12, 14 could be integral with the upper segment 26 of the second stent 14 and connected to lower segment 24 of the first segment 26. Alternatively, the bridge 18 could be integral with the

lower segment 24 of the first stent 12 and connected to the upper segment 26 of the second stent 14.

In yet other embodiments, bridges 18 could be separate pieces of materials which are separately connected to segments 22, 24, 26, 28 such as by welding, adhesion, or other bonding method. In all of these embodiments, the first stent 12 can be made from different pieces of material than the second stent 14. A tube from which the first stent 12 may be made (e.g. by laser cutting techniques) may comprise a smaller diameter than a tube from which the second stent 14 may be made. The respective tubes may or may not be made of the same material. Alternatively, the first and second stent may be formed from a single piece of material.

When the segments 26 and 28 of the second stent 14 are made from tubes of a smaller diameter than the segments 22 and 24 of the first stent 12, the radial force of the first stent segments 22 and 24 is larger than the radial force of the second stent segments 26 and 28, especially at larger cross sections.

Accordingly, bridges 18 can be made from one of these tubes, and thus be integral with segments 22 and 24 or segments 26 and 28. Alternatively, the bridges 18 can be separate pieces of material.

In further embodiments, bridges 18 are omitted such that the individual segments are spaced as desired during installation and use. These individual segments are still delivered and implanted in the same core and sheath assembly.

The bridges 18 between two consecutive segments could be greater or smaller in number than six, and they could have a shape other than an omega shape, permitting their multidirectional elasticity, and in particular a V shape or W shape.

For example, Figure 8 shows an alternative embodiment of the stent system 10 with first 12 and second 14 stents shown in their unconstrained, expanded states. According to this embodiment, each stent 12, 14 may be divided into two segments 22, 24 and 26, 28 and may include one or more flexible bridges 18 connecting the first 12 and second stents 14 to one another. In this embodiment, the two consecutive segments 22, 24 and 26, 28 of the first and second stents 12 and 14, are connected by a plurality (e.g. six) omega-shaped bridges 50. The curved central part 52 of these bridges 50 may have a multidirectional elasticity permitting the appropriate longitudinal orientation of the various segments in relation to one another. The advantage of these bridges 50 is that they provide the stent

with longitudinal continuity, which facilitates the passage of the stent system into a highly curved zone and which eliminates the need to reduce this curvature, (which may be dangerous in the cases of arteriosclerosis).

Thus, the stent system 10 of Figure 8 can comprise several segments 22, 24, 26, 28 5 placed one after the other, in order to ensure supplementary support and, if need be, to increase the hold of the stents in the bifurcation 30. The upper segment 26 of the second stent 14 could have an axis coincident with the longitudinal axis of the first stent, and not oblique in relation to this axis, if such is rendered necessary by the anatomy of the bifurcation which is to be treated.

10 Alternatively, the lower segment 24 of the first stent 12 could itself have, in the expanded state, a widened shape similar to that of the second stent and corresponding to the shape of the widened connecting zone (increasing diameter in the proximal direction) by which, in certain bifurcations, the secondary conduits 34 are connected to the widened transition zone 46. Thus, the lower segment 24 of the first stent 12, or the entire first stent 15 12 may have a first diameter at its distal end, and a second, larger diameter at its proximal end with a linear or progressive curve (flared) taper in between. According to this embodiment, this segment 24 would thus have a shape corresponding to the shape of this widened connecting zone, and would ensure perfect support thereof.

One method of making a self-expanding stent is by appropriate cutting of a sheet of 20 nickel/titanium alloy (for example, an alloy known by the name NITINOL may appropriately be used) into a basic shape, then rolling the resulting blank into a tubular form. The blank may be held in a cylindrical or frustoconical form by welding the opposing edges of this blank which come into proximity with each other. The stent(s) may also be formed by laser cutting from metal tube stock as is known in the art. Alternatively, 25 a stent may be formed by selectively bending and forming a suitable cylindrical or noncylindrical tubular shape from a single or multiple wires, or thin strip of a suitable elastic material. Those skilled in the art will understand that many methods and materials are available for forming stents, only some of which are described herein.

Some Nickel Titanium alloys are malleable at a temperature of the order of 10 °C 30 but can recover a neutral shape at a temperature substantially corresponding to that of the human body. Figure 2 shows the stent system 10 disposed on a delivery catheter in a state of radial contraction. In one embodiment, a self-expanding stent may be contracted by

cooling its constituent material of nickel-titanium or other shape-memory alloy to a temperature below its transformation temperature. The stent may later be expanded by exposing it to a temperature above the transformation temperature. In the present use, a shape-memory alloy with a transformation temperature at or below normal body 5 temperature may be used. Those skilled in the art will recognize that a self-expanding stent made of a substantially elastic material may also be mechanically contracted from its expanded shape by applying a radial compressive force. The stent may then be allowed to expand under the influence of the material's own elasticity. Nickel titanium and other alloys such as such as Silver-Cadmium (Ag-Cd), Gold-Cadmium (Au-Cd) and Iron-Platinum 10 (Fe₃-Pt), to name but a few offer desirable superelastic qualities within a specific temperature range.

In one embodiment, the contraction of a stent may cause the mesh cell edges 48 to pivot in relation to the transverse edges 49 of the mesh cells 36 in such a way that the mesh cells 36 have, in this state of contraction, a substantially rectangular shape. Those skilled in 15 the art will recognize that other materials and methods of manufacturing may be employed to create a suitable self-expanding stent.

Alternatively, the stents used may be manually expandable by use of an inflatable dilatation balloon with or without perfusion as will be discussed further below. Many methods of making balloon-expandable stents are known to those skilled in the art. 20 Balloon expandable stents may be made of a variety of bio-compatible materials having desirable mechanical properties such as stainless steel and titanium alloys. Balloon-expandable stents preferably have sufficient radial stiffness in their expanded state that they will hold the vessel wall at the desired diameter. In the case of a balloon-expandable second stent 14, the balloon on which the second stent 14 is disposed may be specifically 25 adapted to conform to the desired shape of the second stent 14. Specifically, such a balloon will preferably have a larger diameter at a distal end than at a proximal end.

The present discussion thus provides a pair of dissimilar stents permitting the treatment of a pathological condition in the area of a bifurcation 30. This system has the many advantages indicated above, in particular those of ensuring a perfect support of the 30 vessel wall and of being relatively simple to position.

For the sake of simplification, the segment which has, in the unconstrained expanded state, a cross section substantially greater than the cross section of one of the

secondary conduits will be referred to hereinafter as the "secondary segment", while the segment which has, in the expanded state, a truncated shape will be referred to hereinafter as the "truncated segment."

5 The secondary segment is intended to be introduced into the secondary conduit in the contracted state and when expanded will preferably bear against the wall of the conduit. This expansion not only makes it possible to treat a narrowing or a dissection situated in the area of the conduit, but also to ensure perfect immobilization of the apparatus in the conduit.

10 In this position, the truncated segment bears against the wall of the conduit delimiting the widened transitional zone of the bifurcation, which it is able to support fully. A narrowing or a dissection occurring at this site can thus be treated by means of this apparatus, with uniform support of the vascular wall, and thus without risk of this wall being damaged.

15 The two segments may be adapted to orient themselves suitably in relation to each other upon their expansion.

20 Advantageously, at least the truncated segment may be covered by a membrane (for example, Dacron® or ePTFE) which gives it impermeability in a radial direction. This membrane makes it possible to trap between it and the wall of the conduit, the particles which may originate from the lesion being treated, such as arteriosclerotic particles or cellular agglomerates, thus avoiding the migration of these particles in the body. Thus, the apparatus can additionally permit treatment of an aneurysm by guiding the liquid through the bifurcation and thereby preventing stressing of the wall forming the aneurysm.

25 The segments can be made from tubes of material of a different diameter, as discussed above, with the tube for the truncated segment having a larger diameter than the tube for the secondary segment. The tubes may be made from the same material. The use of tubes of different diameters can result in the truncated segment having a larger radial force, especially at larger diameters.

30 The apparatus can comprise several secondary segments, placed one after the other, to ensure supplementary support of the wall of the secondary conduit and, if need be, to increase the anchoring force of the stent in the bifurcation. To this same end, the apparatus can comprise, on that side of the truncated segment directed toward the principal conduit, at

least one radially expandable segment having, in the expanded state, a cross section which is substantially greater than the cross section of the principal conduit.

These various supplementary segments may or may not be connected to each other and to the two aforementioned segments by means of flexible links, such as those indicated 5 above.

The flexible links can be integral with one of the segments and separately connected to the other segment, or the flexible links can be separate pieces of material separately connected to both segments, such as by welding.

Preferably, the flexible link between two consecutive segments is made up of one or 10 more bridges of material connecting the two adjacent ends of these two segments. Said bridge or bridges are advantageously made of the same material as that forming the segments.

Each segment may have a meshwork structure, the meshes being elongated in the longitudinal direction of the stent, and each one having a substantially hexagonal shape; the 15 meshes of the truncated segment may have a width which increases progressively in the longitudinal sense of the stent, in the direction of the end of this segment having the greatest cross section in the expanded state.

This increase in the width of the meshes is the result of an increase in the length of the edges of the meshes disposed longitudinally and/or an increase in the angle formed 20 between two facing edges of the same mesh.

In addition, the truncated segment can have an axis not coincident with the longitudinal axis of the secondary segment, but oblique in relation to this axis, in order to be adapted optimally to the anatomy of the bifurcation which is to be treated. In this case, the widths of the meshes of the truncated segment also increase progressively, in the 25 transverse sense of the stent, in the direction of a generatrix diametrically opposite that located in the continuation of the bridge connecting this segment to the adjacent segment.

The apparatus can be made of a metal with shape memory, which becomes malleable, without elasticity, at a temperature markedly lower than that of the human body, in order to permit retraction of the apparatus upon itself, and to allow it to recover its 30 neutral shape at a temperature substantially corresponding to that of the human body. This metal may be a nickel/titanium alloy known by the name NITINOL.

The deployment catheter for positioning the stent or stents comprises means for positioning the stents and means for permitting the expansion of the stents when the latter are in place. These means can comprise a catheter having a removable sheath in which the stent is placed in the contracted state, when this stent is made of an elastic material, or a support core comprising an inflatable balloon on which the stent is placed, when this stent is made of a nonelastic material.

5 In either case, this equipment comprises, according to the invention, means with which it is possible to identify and access, through the body of the patient, the longitudinal location of the truncated segment, so that the latter can be correctly positioned in the area of
10 the widened zone of the bifurcation.

In the case where the expansion of this same segment is not uniform in relation to the axis of the stent, the equipment additionally comprises means with which it is possible to identify, through the body of the patient, the angular orientation of the stent in relation to the bifurcation to be treated, so that the part of this segment having the greatest expansion
15 can be placed in a suitable manner in relation to the bifurcation.

Referring to FIG. 9, the stent system is generally deployed using an elongate flexible stent deployment catheter 100. Although primarily described in the context of a multiple stent placement catheter without additional functional capabilities, the stent deployment catheter described herein can readily be modified to incorporate additional features such as
20 an angioplasty balloon or balloons, with or without perfusion conduits, radiation or drug delivery capabilities, or stent sizing features, or any combination of these features, as will be readily apparent to one of skill in the art in view of the disclosure herein.

The elongate delivery catheter 100 generally includes a proximal end assembly 102, a proximal shaft section 110 including a tubular body 111, a distal shaft section 120
25 including a distal tubular body 113, and a distal end assembly 107. The proximal end 102 may include a handpiece 140, having one or more hemostatic valves and/or access ports 106, such as for the infusion of drugs, contrast media or inflation media in a balloon expandable stent embodiment, as will be understood by those of skill in the art. In addition, a proximal guidewire port 172 may be provided on the handpiece 140 in an over the wire embodiment (see Figure 9A). The handpiece 140 disposed at the proximal end of the catheter 100 may also be adapted to control deployment of the stents disposed on the catheter distal end 104 as will be discussed.

The length of the catheter depends upon the desired application. For example, lengths in the area of about 120 cm to about 140 cm are typical for use in coronary applications reached from a femoral artery access. Intracranial or lower carotid artery applications may call for a different catheter shaft length depending upon the vascular access site, as will be apparent to those of skill in the art.

The catheter 100 preferably has as small an outside diameter as possible to minimize the overall outside diameter (e.g. crossing profile) of the delivery catheter, while at the same time providing sufficient column strength to permit distal transluminal advancement of the tapered tip 122. The catheter 100 also preferably has sufficient column strength to allow an outer, axially moveable sheath 114 to be proximally retracted relative to the central core 112 in order to expose the stents 118. The delivery catheter 100 may be provided in either "over-the-wire" or "rapid exchange" types as will be discussed further below, and as will generally be understood by those skilled in the art.

In a catheter intended for peripheral vascular applications, the outer sheath 114 will typically have an outside diameter within the range of from about 0.065 inches to about 0.092 inches. In coronary vascular applications, the outer sheath 114 may have an outside diameter with the range of from about 0.039 inches to about 0.065. Diameters outside of the preferred ranges may also be used, provided that the functional consequences of the diameter are acceptable for the intended purpose of the catheter. For example, the lower limit of the diameter for any portion of catheter 100 in a given application will be a function of the number of guidewire, pullwire or other functional lumen contained in the catheter, together with the acceptable minimum flow rate of dilatation fluid, contrast media or drugs to be delivered through the catheter and minimum contracted stent diameter.

The ability of the catheter 100 to transmit torque may also be desirable, such as to avoid kinking upon rotation, to assist in steering, and in embodiments having an asymmetrical distal end on the proximal stent 14. The catheter 100 may be provided with any of a variety of torque and/or column strength enhancing structures, for example, axially extending stiffening wires, spiral wrapped support layers, or braided or woven reinforcement filaments which may be built into or layered on the catheter 100. See, for example, U.S. Pat. No. 5,891,114 to Chien, et al., the disclosure of which is incorporated in its entirety herein by reference.

Referring to FIG. 11D, there is illustrated a cross-sectional view through the proximal section 106 of the catheter shaft 100 of FIG. 9. The embodiment shown in Figure 11D represents a rapid exchange embodiment, and may comprise a single or multiple lumen extrusion or a hypotube including a pull wire lumen 220. In an over-the-wire embodiment, the proximal section 106 additionally comprises a proximal extension of a guidewire lumen 132 and a pull wire lumen 220. The proximal tube 111 may also comprise an inflation lumen in a balloon catheter embodiment as will be understood by those skilled in the art.

At the distal end 107, the catheter is adapted to retain and deploy one or more stents within a conduit of a human body. With reference to Figures 10A and 12, the distal end assembly 107 of the delivery catheter 100 generally comprises an inner core 112, an axially moveable outer sheath 114, and optionally one or more inflatable balloons 116 (Fig. 12). The inner core 112 is preferably a thin-walled tube at least partially designed to track over a guidewire, such as a standard 0.014 inch guidewire. The outer sheath 114 preferably extends along at least a distal portion 120 of the central core 112 on which the stents 118 are preferably disposed.

The outer sheath 114 may extend over a substantial length of the catheter 100, or may comprise a relatively short length, distal to the proximal guidewire access port 172 as will be discussed. In general, the outer sheath 114 is between about 5 and about 25 cm long.

Referring to Figure 10, the illustrated outer sheath 114 comprises a proximal section 115, a distal section 117 and a transition 119. The proximal section 115 has an inside diameter which is slightly greater than the outside diameter of the tubular body 113. This enables the proximal section 115 to be slideably carried by the tubular body 113. Although the outer sheath 114 may be constructed having a uniform outside diameter throughout its length, the illustrated outer sheath 114 steps up in diameter at a transition 119. The inside diameter of the distal section 117 of outer sheath 114 is dimensioned to slideably capture the one or more stents as described elsewhere herein. In a stepped diameter embodiment such as that illustrated in Figure 10, the axial length of the distal section 117 from the transition 119 to the distal end is preferably sufficient to cover the stent or stents carried by the catheter 100. Thus, the distal section 117 in a two stent embodiment is generally at least about 3 cm and often within the range of from about 5 cm to about 10 cm in length.

The axial length of the proximal section 115 can be varied considerably, depending upon the desired performance characteristics. For example, proximal section 115 may be as short as one or two centimeters, or up to as long as the entire length of the catheter. In the illustrated embodiment, the proximal section 115 is generally within the range of from 5 about 5 cm to about 15 cm long.

The outer sheath 114 and inner core 112 may be produced in accordance with any of a variety of known techniques for manufacturing rapid exchange or over the wire catheter bodies, such as by extrusion of appropriate biocompatible polymeric materials. Known materials for this application include high and medium density polyethylenes, 10 polytetrafluoroethylene, nylons, PEBAK, PEEK, and a variety of others such as those disclosed in U.S. Pat. No. 5,499,973 to Saab, the disclosure of which is incorporated in its entirety herein by reference. Alternatively, at least a proximal portion or all of the length of central core 112 and/or outer sheath 114 may comprise a metal or polymeric spring coil, solid walled hypodermic needle tubing, or braided reinforced wall, as is understood in the 15 catheter and guidewire arts.

The distal portion 117 of outer sheath 114 is positioned concentrically over the stents 118 in order to hold them in their contracted state. As such, the distal portion 117 of the outer sheath 114 is one form of a releasable restraint. The releasable restraint preferably comprises sufficient radial strength that it can resist deformation under the radial outward bias of a self-expanding stent. The distal portion 117 of the outer sheath 114 may comprise 20 a variety of structures, including a spring coil, solid walled hypodermic needle tubing, banded, or braided reinforced wall to add radial strength as well as column strength to that portion of the outer sheath 114. Alternatively, the releasable restraint may comprise other elements such as water soluble adhesives or other materials such that once the stents are 25 exposed to the fluid environment and/or the temperature of the blood stream, the restraint material will dissolve, thus releasing the self-expandable stents. A wide variety of biomaterials which are absorbable in an aqueous environment over different time intervals are known including a variety of compounds in the polyglycolic acid family, as will be understood by those of skill in the art. In yet another embodiment, a releasable restraint 30 may comprise a plurality of longitudinal axial members disposed about the circumference of the stents. According to this embodiment anywhere from one to ten or more axial

members may be used to provide a releasable restraint. The axial members may comprise cylindrical rods, flat or curved bars, or any other shape determined to be suitable.

In some situations, self expanding stents will tend to embed themselves in the inner wall of the outer sheath 114 over time. As illustrated in Figures 9D and 10A, a plurality of 5 expansion limiting bands 121 may be provided to surround sections of the stents 12, 14 in order to prevent the stents from becoming embedded in the material of the sheath 114. The bands 121 may be provided in any of a variety of numbers or positions depending upon the stent design. Figure 10A illustrates the bands positioned at midpoints of each of the four proximal stent sections 127 and each of the five distal stent sections. In an alternative 10 embodiment, the bands 121 are positioned over the ends of adjacent stent sections. The bands 121 may be made of stainless steel, or any other suitable metal or relatively non compliant polymer. Of course, many other structures may also be employed to prevent the self-expanding stents from embedding themselves in the plastic sheath. Such alternative structures may include a flexible coil, a braided tube, a solid-walled tube, or other restraint 15 structures which will be apparent to those skilled in the art in view of the disclosure herein.

The inner surface of the outer sheath 114, and/or the outer surface of the central core 112 may be further provided with a lubricious coating or lining such as Paralene, Teflon, silicone, polyimide-polytetrafluoroethylene composite materials or others known in the art and suitable depending upon the material of the outer sheath 114 and/or central core 112.

20 Figure 10B shows a distal portion of sheath 114 received in an annular recess 230 in the distal tip. As shown, at least the distal portion of the sheath 114 may comprise a two layer construction having an outer tube 213 and an inner tube or coating 212. The exterior surface of the outer tube 213 is preferably adapted to slide easily within the vessels to be treated, while the inner surface is generally adapted to have a low coefficient of static 25 friction with respect to the stents, thus allowing the sheath to slide smoothly over the stents. The outer tube 213 may, for example, be made of or coated with HDPE or PEBAK, and the inner tube 212 may, for example, be made of or coated with HDPE, PTFE, or FEP. In an embodiment in which the inner tube is made with a PTFE liner, however, the distal end 214 of the lubricious inner layer or tube 212 is preferably spaced proximally from the distal end 30 216 of the outer tube 213 by a distance within the range of from about 1 mm to about 3 mm. This helps prevent the stent from prematurely jumping distally out of the sheath during deployment due to the high lubricity of the PTFE surface.

Figure 10 illustrates one embodiment of a sheath retraction system. The system illustrated generally includes a sheath pull wire 222, a pull wire slot 224, a sheath retraction band 226, and an outer sheath 114. The sheath retraction band 226 may be a tubular element thermally or adhesively bonded or otherwise secured to a portion of the outer sheath 114. In the illustrated embodiment, the retraction band 226 comprises a section of stainless steel tubing having an outside diameter of about 0.055 inches, a wall thickness of about 0.0015 inches and an axial length of 0.060 inches. However, other dimensions may be readily utilized while still accomplishing the intended function. The sheath retraction band 226 is positioned within the distal portion 117 of the outer sheath 114, just distally of the diameter transition 119. The retraction band 226 may be connected to the interior surface of the outer sheath 114 by heat fusing a pair of bands 225 to the inside surface of the outer sheath at each end of the retraction band (see Figure 9E). Alternatively, the retraction band 226 can be attached to the outer sheath by using adhesives, epoxies, or by mechanical methods such as crimping and swaging or a combination of these. In this manner, the pull force which would be required to proximally dislodge the retraction band 226 from the outer sheath 114 is greatly in excess of the proximal traction which will be applied to the pull wire 222 in clinical use. The distal end of the pull wire 222 is preferably welded, soldered, bonded, or otherwise secured to the sheath retraction band 226. The pull wire 222 may alternatively be bonded directly to the outer sheath.

The pull wire slot 224 is preferably of sufficient length to allow the sheath 114 to be fully retracted. Thus, the pull wire slot 224 is preferably at least as long as the distance from the distal end of the stent stop 218 to the distal end of the sheath 114 as shown in Figure 10A. Slot lengths within the range of from about 1 cm to about 10 cm are presently contemplated for a two stent deployment system. With the sheath 114 in the distal position as shown, the pull wire slot 224 is preferably entirely covered by the proximal portion 115 of the sheath 114. Alternatively, in an embodiment in which the proximal extension of sheath 114 extends the entire length of the catheter 100, discussed above, it can be directly attached to the control 150, in which case a pull wire 222 and slot 224 as shown might not be used.

In yet another embodiment illustrated for example in Figures 9B and 9C, a pull wire lumen 220 may terminate sufficiently proximally from the retraction band 226 that a slot as shown may not be used.

The pull wire 222 may comprise a variety of suitable profiles known to those skilled in the art, such as round, flat straight, or tapered. The diameter of a straight round pull wire 222 may be between about 0.008" and about 0.018" and in one embodiment is about 0.009". In another embodiment, the pull wire 222 has a multiple tapered profile with 5 diameters of 0.015", 0.012", and 0.009" and a distal flat profile of 0.006" x 0.012". The pull wire 222 may be made from any of a variety of suitable materials known to those skilled in the art, such as stainless steel or nitinol, and may be braided or single strand and may be coated with a variety of suitable materials such as Teflon, Paralene, etc. The wire 222 has sufficient tensile strength to allow the sheath 114 to be retracted proximally relative 10 to the core 112. In some embodiments, the wire 222 may have sufficient column strength to allow the sheath 114 to be advanced distally relative to the core 112 and stents 12, 14. For example, if the distal stent 12 has been partially deployed, and the clinician determines that the stent 12 should be re-positioned, the sheath 114 may be advanced distally relative to the stent 12 thereby re-contracting and capturing that stent on the core.

15 In general, the tensile strength or compressibility of the pull wire 222 may also be varied depending upon the desired mode of action of the outer sheath 114. For example, as an alternative to the embodiment described above, the outer sheath 114 may be distally advanced by axially distally advancing the pull wire 222, to release the stent 118. In a hybrid embodiment, the outer sheath 114 is split into a proximal portion and a distal portion. A pull wire is connected to the proximal portion, to allow proximal retraction to release the proximal stent. A push wire is attached to the distal portion, to allow distal advance, thereby releasing the distal stent. These construction details of the catheter 100 and nature of the wire 222 may be varied to suit the needs of each of these embodiments, as will be apparent to those skilled in the art in view of the disclosure herein.

20 25 The stents 118 are carried on the central support core 112, and are contracted radially thereon. By virtue of this contraction, the stents 118 have a cross section which is smaller than that of the conduits 32 and 34, and they can be introduced into these as will be described below. The stents 118 are preferably disposed on a radially inwardly recessed distal portion 129 of the central core 112 having a smaller diameter than the adjacent 30 portions of the core 112. See Figure 12. This recess 129 is preferably defined distally by a distal abutment such as a shoulder 124 which may be in the form of a proximally facing surface on a distal tip 122. Distal tip 122 has an outer diameter smaller than that of the

stents 118 when the stents are expanded, but greater than the diameter of the stents 118 when they are contracted. This abutment 124 consequently prevents distal advancement of the stents 118 from the core 112 when the stents 118 are contracted.

Proximal movement of the stents 118 relative to the core 112 is prevented when the 5 stents are in the radially contracted configuration by a proximal abutment surface such as annular shoulder 125. The distal abutment 124 and proximal abutment 125 may be in the form of annular end faces formed by the axial ends of annular recess 129 in the core 112, for receiving the compressed stents 118. See Figure 12. In one embodiment, illustrated in Figure 10A, the proximal abutment 125 is carried by a stent stop 218. Stent stop 218 may 10 be integral with or attached to the central core 112, and has an outside diameter such that it is in sliding contact with the inside surface of outer sheath 114. The compressed stent 14 will thus not fit between the stop 218 and the outer sheath 114.

The deployment device 100 typically has a soft tapered tip 122 secured to the distal 15 end of inner core 112, and usually has a guidewire exit port 126 as is known in the art. The tapered distal tip 122 facilitates insertion and atraumatic navigation of the vasculature for positioning the stent system 118 in the area of the bifurcation to be treated. The distal tip 122 can be made from any of a variety of polymeric materials well known in the medical 20 device arts, such as polyethylene, nylon, PTFE, and PEBAK. In the embodiment shown in Figure 10, the distal tip 122 comprises an annular recess 230 sized and adapted to allow a distal portion of the outer sheath 114 to reside therein such that the transition between the tip and the outer sheath comprises a smooth exterior surface.

The distal tip 122 tapers in one embodiment from an outside diameter which is substantially the same as the outer diameter of the outer sheath 114 at the proximal end 128 of the tip 122 to an outside diameter at its distal end 130 of slightly larger than the outside 25 diameter of a guidewire. The overall length of the distal tip 122 in one embodiment of the delivery catheter 100 is about 3 mm to about 12 mm, and in one embodiment the distal tip is about 8 mm long. The length and rate of taper of the distal tip 122 can be varied depending upon the desired trackability and flexibility characteristics. The tip 122 may taper in a linear, curved or any other manner known to be suitable.

With reference to Figures 11B and 12, a distal portion of the central core 112 30 preferably has a longitudinal axial lumen 132 permitting slideable engagement of the core 112 on a guidewire 170. The guidewire lumen 132 preferably includes a proximal access

port 172 and a distal access port 126 through which the guidewire may extend. The proximal access port 172 may be located at a point along the length of the catheter 100, as shown in Figures 11A and 11B, and discussed below (rapid exchange), or the proximal access port 172 may be located at the proximal end 102 of the catheter 100 (over the wire).

5 In a rapid exchange embodiment, the proximal access port 172 is generally within about 25 cm of the distal access port 126, and preferably is between about 20 cm and about 30 cm of the distal access port 126. The guidewire lumen 132 may be non-concentric with the catheter centerline for a substantial portion of the length of the guidewire lumen 132.

Figures 11A and 11B illustrate a transition between a proximal shaft tube 111 and a distal shaft tube 113 including a proximal guidewire access port 172 and a guidewire lumen 132. The guidewire lumen 132 may extend through a coextrusion, or may be a separate section of tubing which may be bonded, bound by a shrink wrap tubing, or otherwise held relative to the proximal shaft tube 111.

In the construction shown in cross-section in Figure 11B, a proximal shaft tube 111 having a pull wire lumen 220 is joined to a distal shaft tube 113 having a continuation of pull wire lumen 220 as well as a guidewire lumen 132. In the illustrated embodiment, the proximal shaft tube 111 extends distally into the proximal end of connector tubing 230. A mandrel is positioned within each lumen, and shrink tubing 236 is heated to bond the joint. An opening is subsequently formed in the shrink wrap to produce proximal access port 172 which provides access to the guidewire lumen 132.

In one embodiment, the proximal shaft tube 111 comprises a stainless steel hypodermic needle tubing having an outside diameter of about 0.025" and a wall thickness of about 0.003". The distal end 123 of the hypotube is cut or ground into a tapered configuration. The axial length of the tapered zone may be varied widely, depending upon the desired flexibility characteristics of the catheter 100. In general, the axial length of the taper is within the range of from about 1 cm to about 5 cm, and, in one embodiment, is about 2.5 cm. Tapering the distal end of the hypotube at the transition with the distal portion of the catheter provides a smooth transition of the flexibility characteristics along the length of the catheter, from a relatively less flexible proximal section to a relatively 25 more flexible distal section as will be understood by those of skill in the art.

Referring to Figure 12, a guidewire 170 is illustrated as positioned within the guidewire lumen 132. As can be appreciated by those of skill in the art, the diameter of the

guidewire 170 is illustrated as slightly smaller (e.g., by about 0.001-0.003 inches) than the inside diameter of the guidewire lumen 132. Avoiding a tight fit between the guidewire 170 and inside diameter of guidewire lumen 132 enhances the slideability of the catheter over the guidewire 170. In ultra small diameter catheter designs, it may be desirable to coat 5 the outside surface of the guidewire 170 and/or the inside walls of the guidewire lumen 132 with a lubricious coating to minimize friction as the catheter 100 is axially moved with respect to the guidewire 170. A variety of coatings may be utilized, such as Paralene, Teflon, silicone, polyimide-polytetrafluoroethylene composite materials or others known in the art and suitable depending upon the material of the guidewire 170 or central core 112.

10 As shown in Figure 12, an inflation lumen 134 may also extend throughout the length of the catheter 100 to place a proximal inflation port in fluid communication with one or more inflatable balloons 116 carried by the distal end of the catheter.

15 The inflatable balloon 116, if present, may be positioned beneath one or both stents, such as stent 14 as illustrated in Figure 12 or proximally or distally of the stent, depending upon the desired clinical protocol. In one embodiment, as illustrated in Figure 12, the stent may be a self expandable stent which is initially released by proximal retraction by the outer sheath 114 as has been discussed. The balloon 16 is thereafter positioned in concentrically within the stent, such that it may be inflated without repositioning the catheter to enlarge and/or shape the stent. Post stent deployment dilatation may be 20 desirable either to properly size and or shape the stent, or to compress material trapped behind the stent to increase the luminal diameter (e.g. angioplasty). In an alternate mode of practicing the invention, angioplasty is accomplished prior to deployment of the stent either by a balloon on the stent deployment catheter 100 or by a separate angioplasty balloon catheter (or rotational artherectomy, laser or other recanalization device). The stent deployment catheter 100 is thereafter positioned within the dilated lesion, and the stent is 25 thereafter deployed. Thus, balloon dilatation can be accomplished using either the deployment catheter 100 or separate procedural catheter, and may be accomplished either prior to, simultaneously with, or following deployment of one or more stents at the treatment site.

30 As seen in Figure 9 and 9B, the catheter also includes a handpiece 140 at the proximal end of the catheter 100. The handpiece 140 is adapted to be engaged by the clinician to navigate and deploy the stent system 118 as will be described below. The

handpiece 140 preferably includes a control 150 adapted to control and indicate a degree of deployment of one or both stents. The control 150 is typically in mechanical communication with the sheath 114 such that proximal retraction of the control 150 results in proximal retraction of the sheath 114. Those skilled in the art will recognize that distal motion, rotational movement of a rotatable wheel, or other motion of various controls 150 may alternatively be employed to axially move such as distally advance or proximally retract the sheath 114 to expose the stents.

The illustrated control 150 is preferably moveable from a first position to a second position for partial deployment of the first stent 12, and a third position for complete deployment of the first stent 12. A fourth and a fifth positions are also provided to accomplish partial and complete deployment of the second stent 14. The control 150 may include indicia 160 adapted to indicate the amount of each stent 12 or 14 which has been exposed as the sheath 114 is retracted relative to the core 112. The indicia 160 may include dents, notches, or other markings to visually indicate the deployment progress. The control 150 may also or alternatively provide audible and/or tactile feedback using any of a variety of notches or other temporary catches to cause the slider to "click" into positions corresponding to partial and full deployment of the stents 12, 14. Alignable points of electrical contact may also be used. Those skilled in the art will recognize that many methods and structures are available for providing a control 150 as desired.

The catheter 100 may include a plurality of radiopaque markers 250 (seen best in Figures 2, 10, and 10A) impressed on or otherwise bonded to it, containing a radiopaque compound as will be recognized by those skilled in the art. Suitable markers can be produced from a variety of materials, including platinum, gold, barium compounds, and tungsten/rhenium alloy. Some of the markers 250A may have an annular shape and may extend around the entire periphery of the sheath 114. The annular markers 250A may be situated, in the area of the distal end of the first stent 12, the distal end of the second stent 14, and in the area of the bridge 18 (FIG. 1) or space separating the stents 12, 14. A fourth marker 252 may be situated at substantially the halfway point of the generatrix of the lower segment of the second stent 14 situated in the continuation of the bridge 18 and of the 30 diametrically opposite generatrix. Figure 2 shows a marker 252 with a diamond shape and a small thickness provided along the outer sheath 114 at a desirable position for determining the rotational position of the catheter within the bifurcation. The markers 250

and 252 may be impressed on the core 112, on the sheath 114, or directly on the stents 12, 14 such as on the bridge 18, and not on the sheath 114.

With reference to Figures 10 and 10A, three markers 253 are shown disposed at a distal end of the second stent 14 and spaced at 120° relative to one another. Three markers 254 are also disposed at a proximal end of the first stent 12, and spaced at 120° relative to one another. Each stent 12, 14 also includes a single marker 210 at its opposite end (e.g. the first stent 12 has a single marker 210 at its distal end, and the second stent 14 has a single marker 210 at its proximal end). Of course, other marker arrangements may be used as desired by the skilled artisan.

10 A central marker 252 makes it possible to visualize, with the aid of a suitable radiography apparatus, the position of a bridge 18 separating the two stents 12, 14. Thus allowing a specialist to visualize the location of the second stent 14 so that it can be correctly positioned in relation to the widened zone 46. The end markers 250A allow a specialist to ensure that the stents 12, 14 are correctly positioned, respectively, in the 15 main/principal conduit 32 and the secondary/branch conduit 34.

20 A diamond-shaped marker 252 as shown in Figure 2 is, for its part, visible in a plan view or an edge view, depending on whether it is oriented perpendicular or parallel to the radius of the radiography apparatus. It thus makes it possible to identify the angular orientation of the stents 12, 14 in relation to the bifurcation 30, so that the part of the second stent 14 having the greatest expansion can be placed in an appropriate manner in relation to the widened transition zone 46.

25 Methods of positioning and deploying a pair of dissimilar stents in an area of a bifurcation will now be discussed with reference to Figures 3-6 and 13-17. Although portions of the following discussion refer to delivery of two dissimilar stent portions, those skilled in the art will recognize that a larger or smaller number of stents, and/or stents having similar expanded configurations may also be used while realizing certain aspects of the present invention.

30 A method of delivering a stent system as described above generally and illustrated in Figures 13-17 includes locating the bifurcation 30 to be treated, providing a suitable delivery catheter 100, positioning the distal portion 107 of a delivery catheter with stents 12, 14 disposed thereon in the branch of the bifurcation to be treated, partially deploying the first stent 12 in a branch vessel 34, observing and adjusting the position of the first stent

12 if necessary, then fully deploying the first stent 12. The second stent 14 is partially deployed, and preferably the position is again observed such as by infusing contrast media through the pull wire lumen 220 under fluoroscopic visualization. The position of the second stent 14 may be adjusted if necessary, and finally the second stent 14 is fully 5 deployed. Methods of navigating catheters through blood vessels or other fluid conduits within the human body are well known to those skilled in the art, and will therefore not be discussed herein.

The delivery catheter 100 may be constructed according to any of the embodiments described above such that the stents 12, 14 may be selectively deployed by axially 10 displacing the outer sheath 114 along the delivery catheter, thereby selectively exposing the stent system 10. This may be accomplished by holding the sheath 114 fixed relative to the bifurcation, and selectively distally advancing the central core 112. Thus, the present invention contemplates deploying one or more stents by distally advancing the central core (inner sheath) rather than proximally retracting the outer sheath as a mode of stent 15 deployment. The stent system may alternatively be deployed by holding the central core fixed relative to the bifurcation and selectively proximally retracting the sheath 114. The catheter may also be adapted to allow the sheath to be advanced distally, thereby re-contracting the partially deployed stents on the central core 112 to allow repositioning or removal.

20 In order to visualize the position of a partially-deployed stent with a suitable radiographic apparatus, a contrast media may be introduced through the catheter to the region of the stent placement. Many suitable contrast media are known to those skilled in the art. The contrast media may be introduced at any stage of the deployment of the stent system 10. For example, a contrast media may be introduced after partially deploying the 25 first stent 12, after fully deploying the first stent 12, after partially deploying the second stent 14, or after fully deploying the second stent 14.

The degree of deployment of the stent system 10 is preferably made apparent by the indicators on the handpiece 140 as described above. The handpiece 140 and outer sheath are preferably adapted such that a motion of a control on the handpiece 140 results in 30 proximal motion of the outer sheath 114 relative to the distal tip 122 and the stents 12, 14. The handpiece 140 and sheath 114 may also be adapted such that the sheath may be advanced distally relative to the stents 12, 14, thus possibly re-contracting one of the stents

12, 14 on the core 112. This may be accomplished by providing a pull wire 222 having a distal end 223 attached to a portion of the outer sheath 114, and a proximal end adapted to be attached to the handpiece 140. Alternatively, the handpiece 140 may be omitted, and the retraction wire 222 may be directly operated by the clinician.

5 In an alternative embodiment, indicated by Figures 4-6, the first and/or second stent 12, 14 may be deployed in a single motion, thus omitting the step of re-positioning the stent 12, 14 before fully deploying it. The sheath 114 is then progressively withdrawn, as is shown in Figures 5 and 6, in order to permit the complete expansion of the stents 12, 14.

10 In a preferred embodiment, the second stent 14 is placed in close proximity to the first stent 12. For example, the distal end 38 of the second stent 14 may be placed within a distance of about 4 mm of the proximal end 42 of the first stent 12, more preferably this distance is less than about 2 mm, and most preferably the first and second stents 12, 14 are placed within 1 mm of one another. Those skilled in the art will recognize that the relative positioning of the first and second stents 12, 14 will at least partially depend on the 15 presence or absence of a bridge 18 as discussed above. The axial flexibility of any bridge 18 will also affect the degree of mobility of one of the stents relative to the other. Thus, a stent system 10 will preferably be chosen to best suit the particular bifurcation to be treated.

20 As mentioned above, the stents 12, 14 may be self-expanding or balloon-expandable (e.g. made of a substantially non-elastic material). Thus the steps of partially deploying the first and/or the second stent may include introducing an inflation fluid into a balloon on which a stent is disposed, or alternatively the stent may be allowed to self-expand. In the case of a balloon-expandable second stent 14, the balloon 116 (FIG. 12A) on which the second stent 14 is disposed may be specifically adapted to correspond to the particular shape of the second stent 14. Specifically, such a balloon will preferably have a larger 25 diameter at a distal end than at a proximal end.

After complete expansion of the stents 12, 14, the distal end of the delivery catheter 100 including the core 112 and the guidewire 170 may be withdrawn from the conduits and the vasculature of the patient. Alternatively, additional stents may also be provided on a delivery catheter, which may also be positioned and deployed in one or both branches of the 30 bifurcation. For example, after deploying the second stent 14 as shown in Figure 6 or 17, the catheter 100 and guidewire 170 may be retracted and re-positioned in the second branch vessel such that a third stent may be positioned and deployed therein.

Referring to Figure 18, a second branch stent 13 may be deployed in the second branch, such that both branch vessels in the bifurcation are fully stented. The second branch stent 13 may be either a self expandable or balloon expandable stent such as those well known in the art and disclosed in part elsewhere herein. The second branch stent 13 5 may be deployed before or after the main stent 14 and/or first branch stent 12. In one application of the invention, the main vessel stent 14 and first branch stent 12 are positioned as has been described herein. A stent deployment catheter (not illustrated) such as a balloon catheter or self expanding stent deployment catheter is transluminally advanced to the bifurcation, and advanced through the main vessel stent 14. The second branch 10 vessel stent 13 may then be aligned in the second branch vessel, such that it abuts end to end, is spaced apart from, or overlaps with the distal end of the main branch stent 14. The second branch vessel stent 13 may then be deployed, and the deployment catheter removed.

As will be clear to those skilled in the art, the stent system 10 and stent delivery system 100 described herein is useful in treating a number of pathological conditions 15 commonly found in vascular systems and other fluid conduit systems of human patients. Treatment with the apparatus can include re-establishing the appropriate diameter of a bifurcation in cases of arteriosclerosis or internal cell proliferation, or in rectifying a localized or nonlocalized dissection in the wall of the conduit, or in re-creating a bifurcation of normal diameter while eliminating the aneurysmal pouch in cases of 20 aneurysm.

One or more of the stents deployed in accordance with the present invention may be coated with or otherwise carry a drug to be eluted over time at the bifurcation site. Any of a variety of therapeutically useful agents may be used, including but not limited to, for example, agents for inhibiting restenosis, inhibiting platelet aggregation, or encouraging 25 endothelialization. Some of the suitable agents may include smooth muscle cell proliferation inhibitors such as rapamycin, angiopeptin, and monoclonal antibodies capable of blocking smooth muscle cell proliferation; anti-inflammatory agents such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, acetyl salicylic acid, and mesalamine, lipoxygenase inhibitors; calcium entry blockers such as 30 verapamil, diltiazem and nifedipine; antineoplastic/antiproliferative/anti-mitotic agents such as paclitaxel, 5-fluorouracil, methotrexate, doxorubicin, daunorubicin, cyclosporine, cisplatin, vinblastine, vincristine, colchicine, epothilones, endostatin, angiostatin,

Squalamine, and thymidine kinase inhibitors; L-arginine; antimicrobials such as triclosan, cephalosporins, aminoglycosides, and nitorfuirantoin; anesthetic agents such as lidocaine, bupivacaine, and ropivacaine; nitric oxide (NO) donors such as lisidomine, molsidomine, NO-protein adducts, NO-polysaccharide adducts, polymeric or oligomeric NO adducts or chemical complexes; anti-coagulants such as D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, enoxaparin, hirudin, Warafin sodium, Dicumarol, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet factors; interleukins, interferons, and free radical scavengers; vascular cell growth promoters such as growth factors, growth factor receptor antagonists, transcriptional activators, and translational promotores; vascular cell growth inhibitors such as growth factor inhibitors (e.g., PDGF inhibitor--Trapidil), growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin; Tyrosine kinase inhibitors, chymase inhibitors, e.g., Tranilast, ACE inhibitors, e.g., Enalapril, MMP inhibitors, (e.g., Ilomastat, Metastat), GP IIb/IIIa inhibitors (e.g., Integritin, abciximab), serotonin antagonist, and 5-HT uptake inhibitors; cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogenous 20 vascoactive mechanisms. Polynucleotide sequences may also function as anti-restenosis agents, such as p15, p16, p18, p19, p21, p27, p53, p57, Rb, nFkB and E2F decoys; thymidine kinase ("TK") and combinations thereof and other agents useful for interfering with cell proliferation. The selection of an active agent can be made taking into account the desired clinical result and the nature of a particular patient's condition and 25 contraindications. With or without the inclusion of a drug, any of the stents disclosed herein can be made from a bioabsorbable material.

The bifurcation 30 shown in Figure 3 has excrescences 35 which create a narrowing in cross section, which impedes the flow of the liquid circulating in the conduits 32 and 34. In the case of a vascular bifurcation, these excrescences are due, for example, to 30 arteriosclerosis or cellular growth. The stent system described herein permits treatment of this bifurcation by re-establishing the appropriate diameter of the conduits 32, 34 and of the widened transition zone 46.

As shown in Figure 7, the stent system 10 can also be used to treat an aneurysm 242. An aneurysm 242 is defined as a localized, pathological, blood-filled dilatation of a blood vessel caused by a disease or weakening of the vessel's wall. Thus it is desirable to provide a "substitute" vessel wall in an area of an aneurysm. For this purpose, the first or 5 second stent 12, 14 may be at least partially covered by a film 240 which is substantially impermeable to the fluid circulating in the conduits 32, 34. Many suitable films are known to those skilled in the art such as polyester, polytetrafluoroethylene (PTFE), high and medium density polyethylenes, etc. The film may be sewn onto the stents 12, 14, or it may be folded around a stent such that as the stent is expanded within the vessel 32, the film 240 10 is trapped and held between the stent and the vessel wall. The stent then guides the liquid through the bifurcation 30 and consequently prevents stressing of the wall forming the aneurysm 242.

In some embodiments, each of the first (cylindrical) stent 12 and second (tapered) stent 14 can be provided on its own individual delivery catheter. With reference to Figures 15 19-22, embodiments of stent delivery systems for use in deploying a single stent for treatment of a pathology at a bifurcation are described below.

Figures 19 and 20 illustrate a system configured to deploy a single stent having a substantially straight or cylindrical shape when in its expanded condition, for example, the stent 12 could be substantially the same as the cylindrical stent 12 of the above 20 embodiments. The system generally includes an elongate delivery catheter 100 substantially as described above and having a single stent 12 disposed on the distal end of the catheter. The stent 12 is surrounded by a retractable sheath 114 having a plurality of radial restraints such as retaining bands 121. In the illustrated embodiment, five retaining bands 121 are provided to retain the stent 12 in a compressed condition. Alternatively, 25 other numbers of retention bands 121 may also be used. For example, one, two, three, four, or six or more retention bands 121 may be used as desired for a particular stent.

Figure 20 shows the system of Figure 19 with a proximal detail of the outer sheath 114. The delivery system for use with the straight stent 12 typically includes a stent stop 218 with an annular shoulder 125 which the proximal end of the stent 12 will abut as the 30 sheath 114 is retracted. As shown in Figure 20, the stent stop 218 will abut the proximal markers 254 (in an embodiment having such markers) as the sheath is retracted by a

proximal force on the pull wire 222 which is attached to the sheath 114 at a retraction band 226.

Figures 21 and 22 illustrate a system configured to deploy a single stent having a substantially conical or otherwise tapered shape when in its expanded condition. For example, the conical stent 14 may be the same or similar to the main branch stent 14 described above. The system of Figure 21 generally includes an elongate delivery catheter 100 substantially as described above and having a single conical stent 14 disposed on the distal end of the catheter 100. The stent 14 is surrounded by a retractable sheath 114, which can include a radial retention structure such as a plurality of retaining bands 121. In the illustrated embodiment, four retaining bands 121 are provided to retain the stent 14 in a compressed condition and resist imprinting into the sheath 114. This number of retaining bands is particularly suited to the conical stent 14 according to one embodiment. Alternatively, other numbers of retention bands 121 may also be used. For example, one, two, three, five, or six or more retention bands 121 may be used as desired for a particular conical stent.

Figure 22 shows the system of Figure 21 with a proximal detail of the outer sheath 114. The delivery system for use with the conical stent 14 can include a stent stop 218 with an annular shoulder 125 disposed within the outer sheath configured to provide an edge against which the stent 14 may abut as the sheath is retracted. The stent stop 218 of the present embodiment illustrated in Figures 21 and 22, comprises a slot 211 in which the proximal marker 210 of the conical stent 14 may rest. By contrast, this slot 211 may be omitted in the embodiment illustrated in Figures 19 and 20 configured for use with a cylindrical stent, or if unnecessary in view of the particular conical stent design.

A delivery system adapted for use with a single stent will often be sized differently from the two-stent delivery system described above as will be apparent to those of skill in the art in view of the disclosure herein. For example, the axial length of the stent receiving recess 129 in a single stent delivery catheter will often be somewhat shorter than a dual-stent catheter. In general, the axial length of the stent receiving recess 129 in a single, tapered stent system for use in a bifurcation of the coronary artery will be within the range of from about 8 mm to about 18 mm, and often within the range of from about 10mm to about 13mm. The tapered stent for use in coronary applications is generally at least 10 mm in axial length, for example, 10mm, 11mm, 12mm, and 13mm can be used. For coronary

applications, the proximal expanded diameter is typically in the range of from about 3mm, to about 6mm, and often from about 3.5 mm to about 5.5mm, and in one embodiment the proximal expanded diameter is about 4.5 mm. The distal expanded diameter is typically in the range of from about 5mm, to about 8mm, and often from about 5.5 mm to about 5

7.5mm. In one embodiment of a tapered stent for use in coronary applications, the distal expanded diameter is about 6.5 mm. In one embodiment, the outer sheath 114 and the inner lumen of a single stent catheter can be about 11 mm shorter than the corresponding parts in a two-stent system.

A tapered stent for use in carotid or biliary applications generally has an axial length 10 in the range of about 15mm up to about 20mm, and often between about 17mm and about 19mm. In one particular embodiment a tapered stent for use in carotid or biliary applications has an axial length of about 18mm. For carotid or biliary applications, the proximal expanded diameter is typically in the range of from about 8mm, to about 12mm, and often from about 9mm to about 11mm, and in one embodiment the proximal expanded 15 diameter is about 10 mm. The distal expanded diameter is typically in the range of from about 11mm, to about 15mm, and often from about 12 mm to about 14 mm. In one embodiment of a tapered stent for use in coronary applications, the distal expanded diameter is about 13 mm. In general, the distal expanded diameter is generally at least about 40% of the axial length, and often the distal expanded diameter is more than 50% of 20 the axial length.

The stent system described may be adapted as mentioned above to treat any of a number of bifurcations within a human patient. For example, bifurcations of both the left and right coronary arteries, the bifurcation of the circumflex artery, the carotid, femoral, iliac, popliteal, renal or other coronary bifurcations. Alternatively this apparatus may be 25 used for nonvascular bifurcations, such as tracheal or biliary bifurcations, for example between the common bile and cystic ducts, or in the area of the bifurcation of the principal bile tract.

Although certain preferred embodiments and examples have been described herein, it will be understood by those skilled in the art that the present inventive subject matter extends 30 beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the present inventive subject matter herein disclosed should not be limited by the

particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.

WHAT IS CLAIMED IS:

1. A deployment system for treating a bifurcation of a main vessel and a first and second branch vessels, comprising:
 - an elongate, flexible body, having a proximal end and a distal end;
 - 5 a first stent carried in a recess on the distal end of the body; and
 - a releasable restraint, for retaining the stent on the flexible body;
 - wherein the distal end of the stent is larger in diameter than the proximal end of the stent in an unconstrained expanded configuration.
2. A deployment system as in Claim 7, further comprising a guidewire lumen
10 extending axially through at least a portion of the flexible body.
3. A deployment system as in Claim 8, wherein the guidewire lumen has a proximal access port and a distal access port, and the proximal access port is positioned along the flexible body, spaced distally apart from the proximal end.
4. A deployment system as in Claim 8, wherein the guidewire lumen has a proximal access port and a distal access port, and the proximal access port is positioned at
15 the proximal end of the flexible body.
5. A deployment system as in Claim 7, wherein the releasable restraint comprises an axially movable control element extending along the length of the flexible body.
- 20 6. A deployment system as in Claim 7, wherein the releasable restraint comprises a tubular sheath.
7. A deployment system as in Claim 7, wherein the releasable restraint comprises a pull wire.
8. A deployment system as in Claim 7, wherein the releasable restraint
25 comprises a dissolvable media.
9. A deployment system as in Claim 7, further comprising a second stent carried by the distal end of the body.
10. A deployment system as in Claim 15, wherein the first and second stents have different expanded geometries from each other.
- 30 11. A deployment system as in Claim 16, wherein the second stent has a substantially cylindrical unconstrained expanded configuration, having a proximal end, a distal end and a substantially constant radius throughout.

12. A deployment system as in Claim 7, wherein the expanded diameter of the first stent tapers radially outwardly in the distal direction.
13. A deployment system as in Claim 15, wherein the first and second stents are carried by the catheter such that release of the stents from the catheter causes the distal end 5 of the first stent and the proximal end of the second stent, as implanted, to be separated by a distance of no more than about 4mm.
14. A deployment system as in Claim 19, wherein the distance is no more than about 2mm.
15. A stent deployment catheter, comprising:
 - 10 an elongate, flexible tubular body, having a proximal end and a distal end;
 - a recess on the body, having an axial length within the range of from about 5 mm to about 20 mm;
 - a noncylindrical, self expandable stent carried by the recess ;
 - a handpiece on the proximal end; and
 - 15 a control on the handpiece, for deploying the stent.
16. A stent deployment catheter as in Claim 23, further comprising a guidewire lumen, in an over the wire configuration.
17. A stent deployment catheter as in Claim 23, further comprising a guidewire lumen, in a rapid exchange configuration.
18. A system for treating a vascular bifurcation of a main vessel into first and second branch vessels, said system comprising:
 - 20 a substantially cylindrical stent configured to be deployed in a first branch vessel which is distal to the bifurcation; and
 - a tapered stent configured to be deployed in the main vessel, proximal to the bifurcation;

25 wherein the tapered stent has a length within the range of from about 10 mm and about 20 mm, and tapers in the distal direction from a smaller proximal diameter to a larger distal diameter which faces the bifurcation.
19. The system for treating a vascular bifurcation as in Claim 21, further comprising a delivery catheter having a proximally retractable outer sheath configured to release at least one of the cylindrical stent and the tapered stent.

20. A system for treating a vascular bifurcation of a main vessel into a first and a second branch vessels, the system comprising:

5 a delivery catheter having a first stent thereon, the first stent having a proximal end and a distal end, a length of at least about 10 mm, and being self expandable to a configuration in which the proximal end has a smaller diameter than the distal end;

a releasable restraint configured to maintain at least one of the first and second stents in a compressed state until delivery of the stent;

10 wherein the distal end of the first stent expands to a diameter that is at least about 105% of the diameter of the proximal end of the first stent.

21. The system for treating a vascular bifurcation of a main vessel into a first and a second branch vessels as in Claim 1, wherein the distal end of the first stent expands to a diameter that is at least about 110% of the diameter of the proximal end of the first stent.

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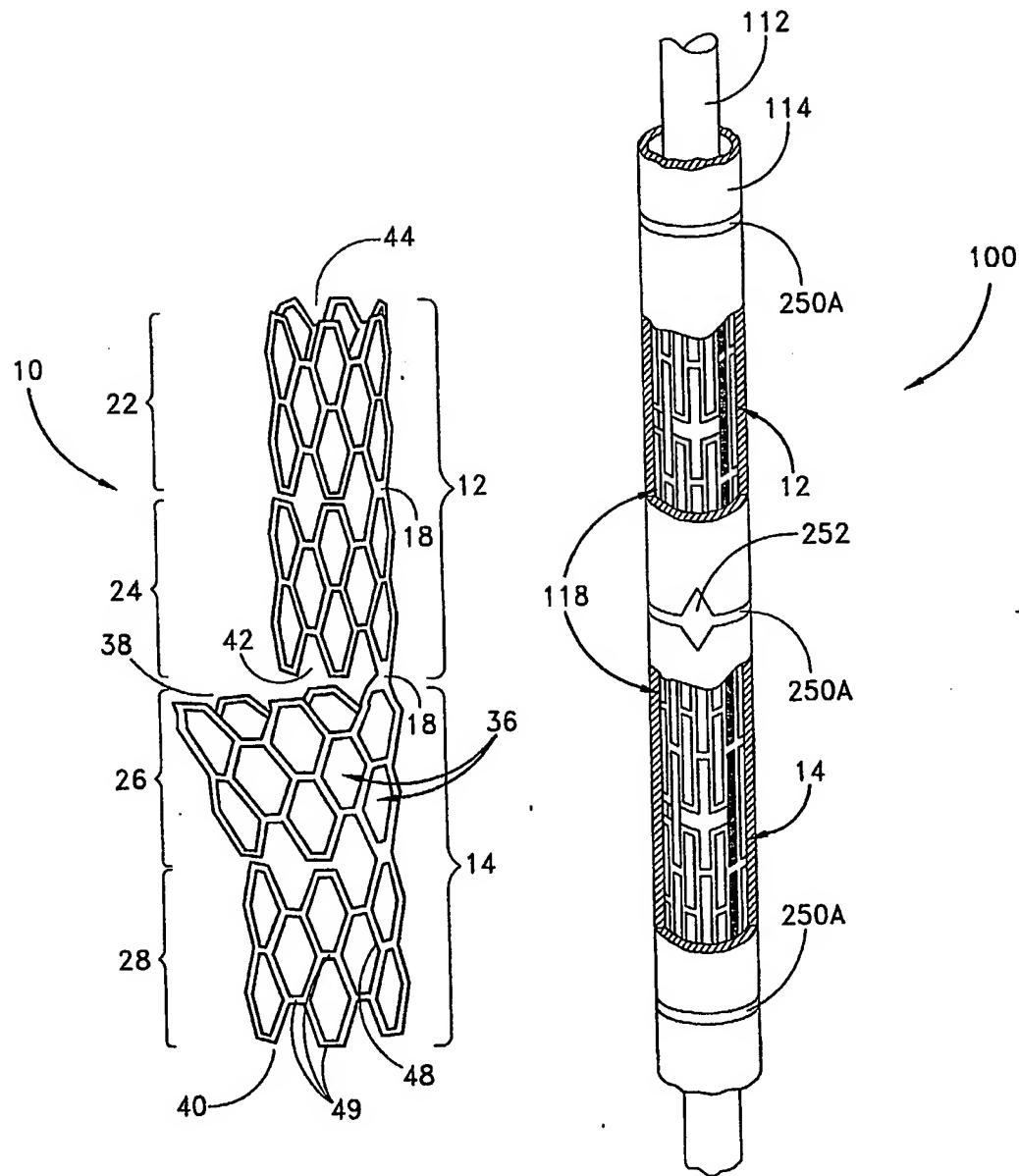


FIG. 1

FIG. 2

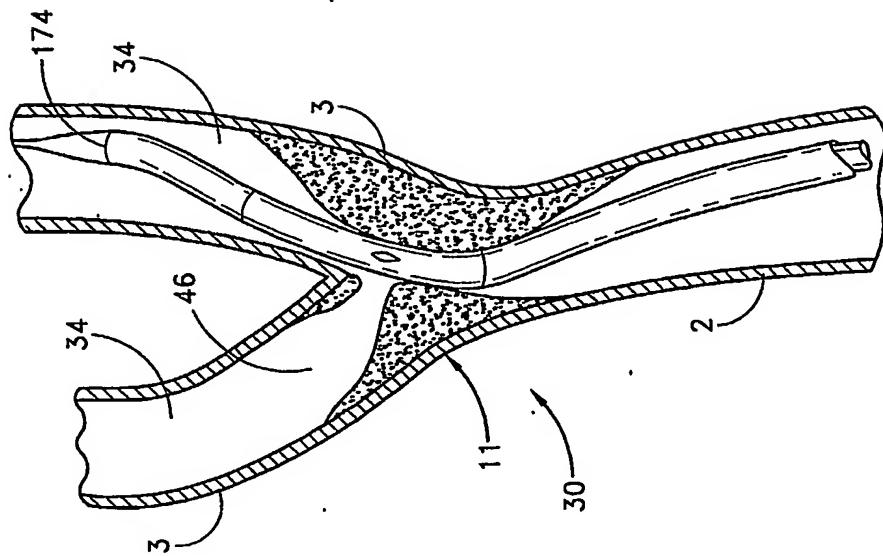


FIG. 4

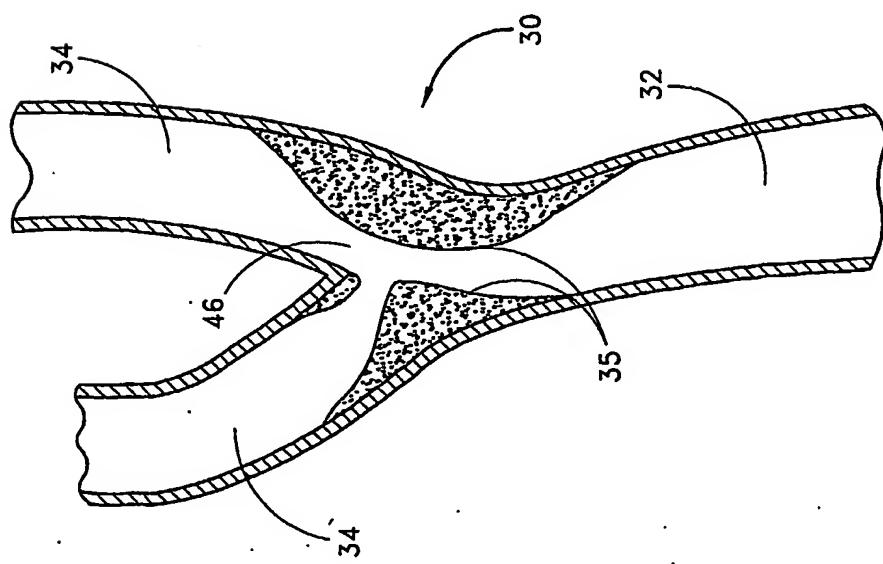


FIG. 3

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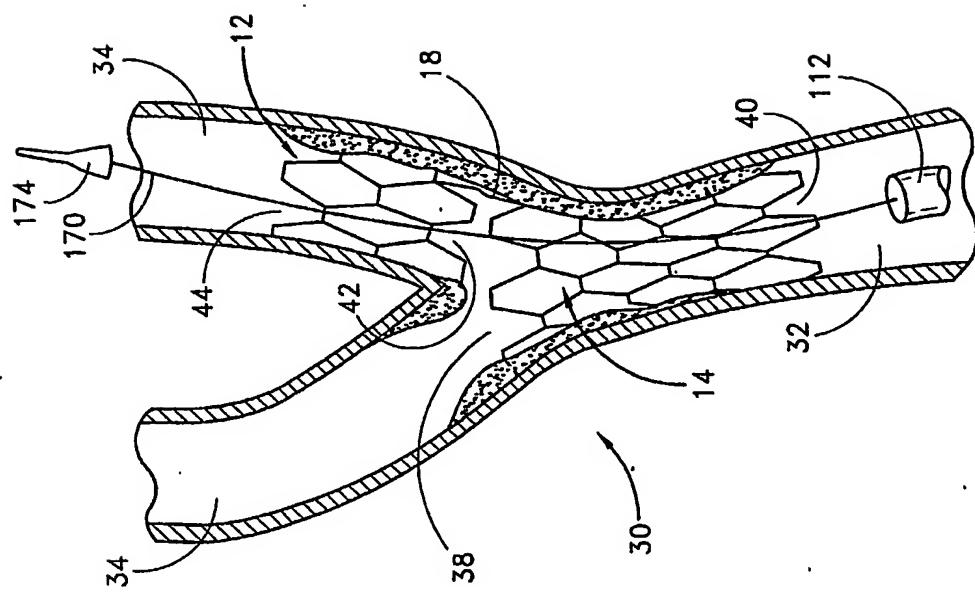


FIG. 6

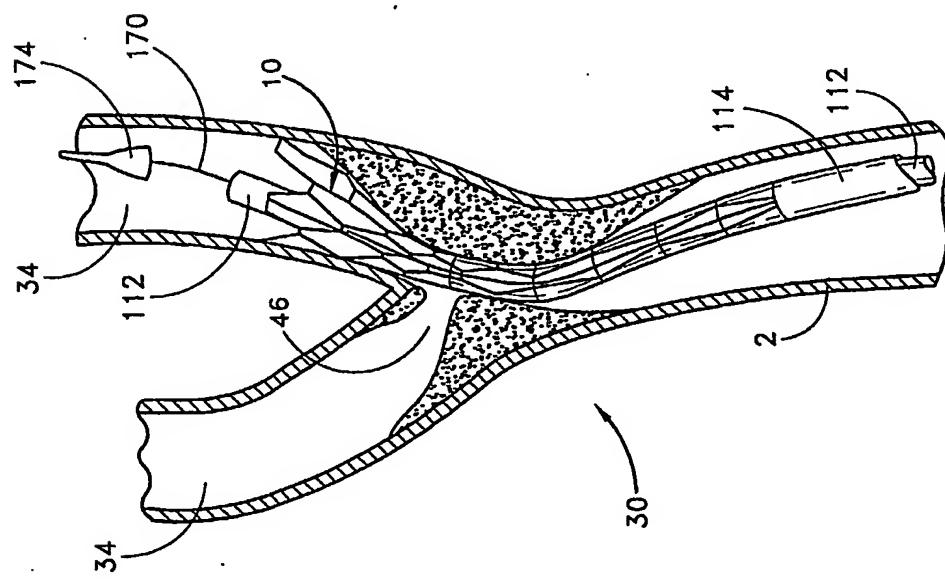


FIG. 5

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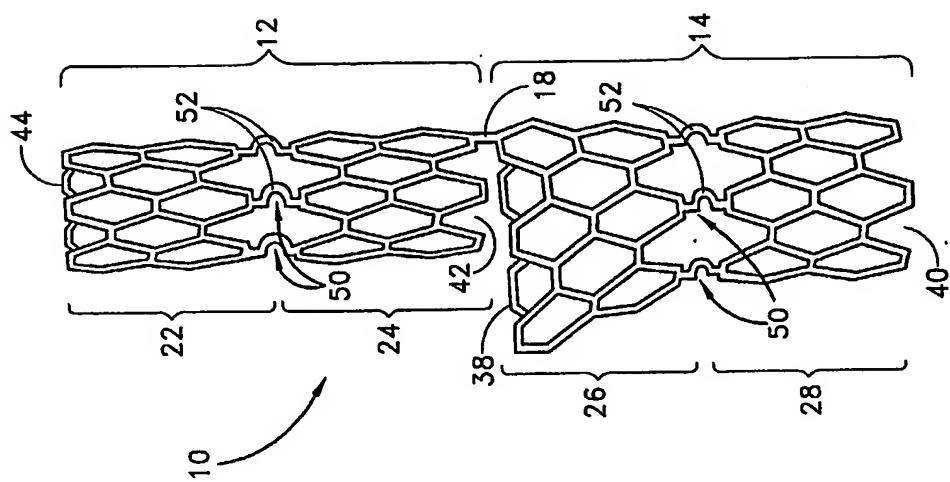


FIG. 8

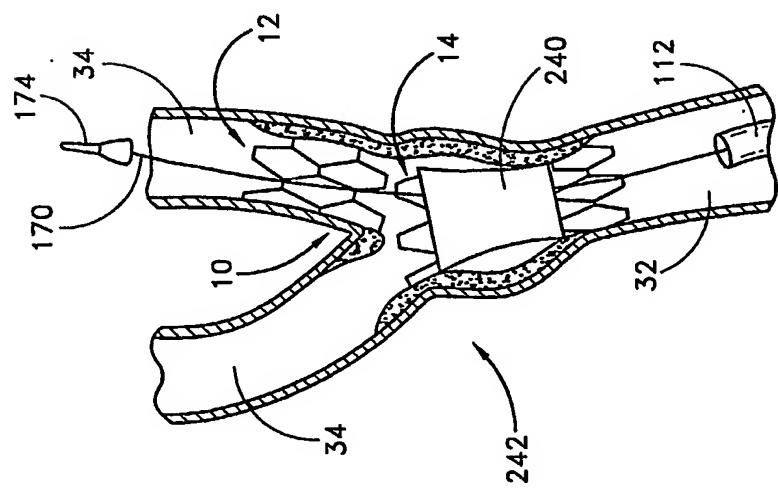


FIG. 7

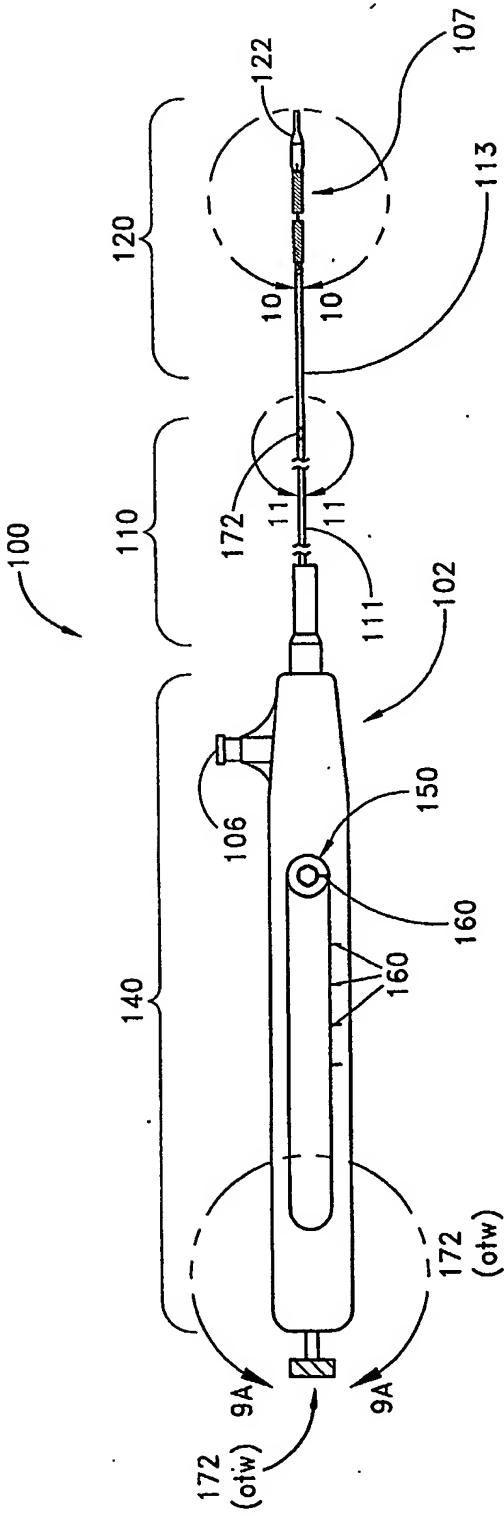


FIG. 9

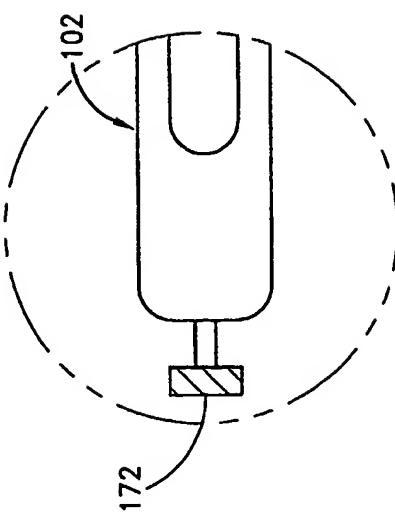


FIG. 9A

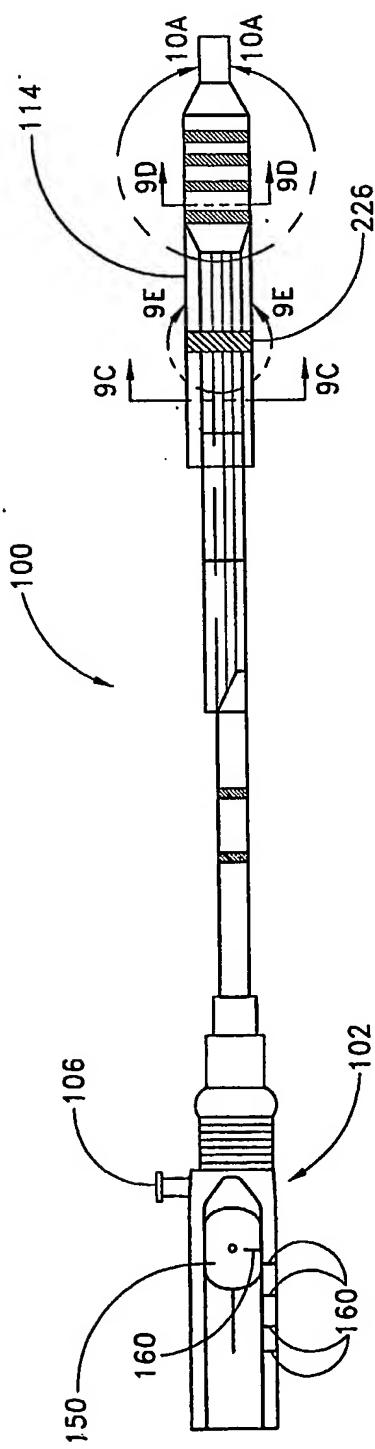


FIG. 9B

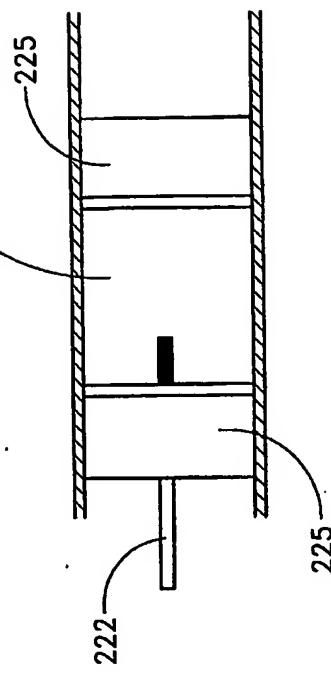


FIG. 226

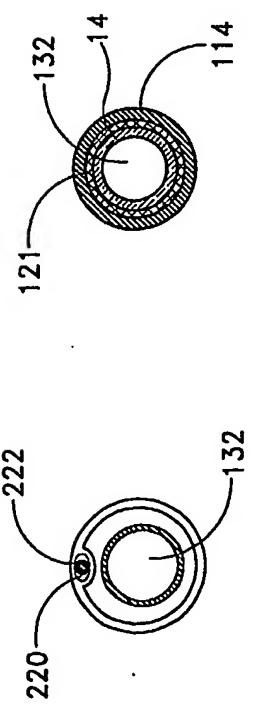


FIG. 9C

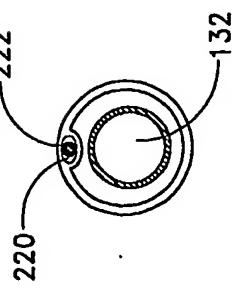


FIG. 9D

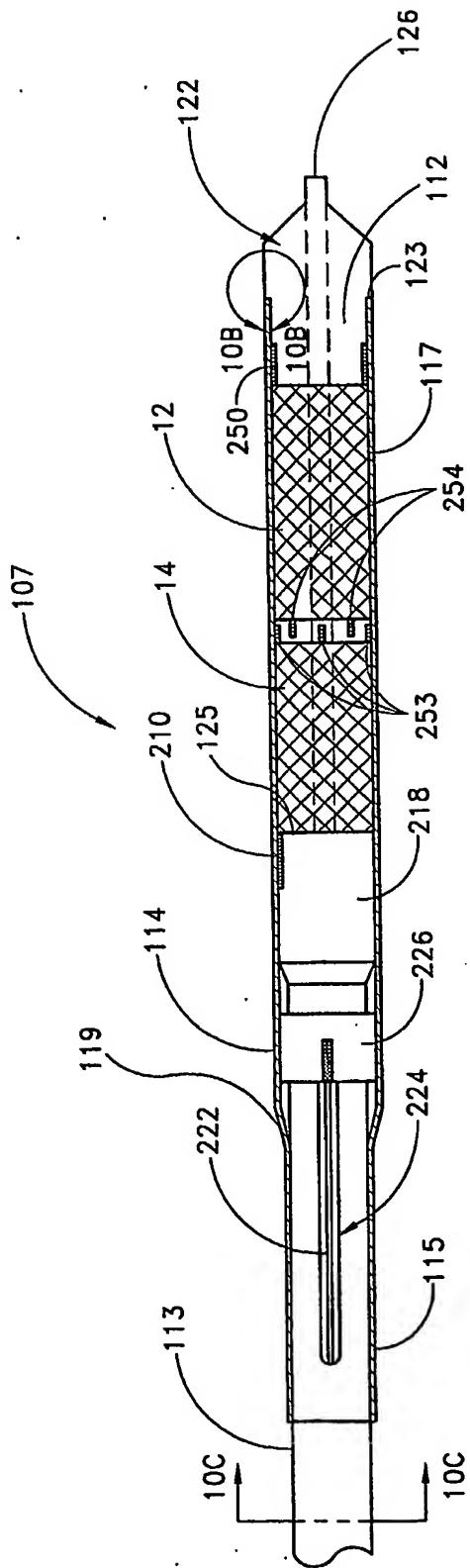


FIG. 10

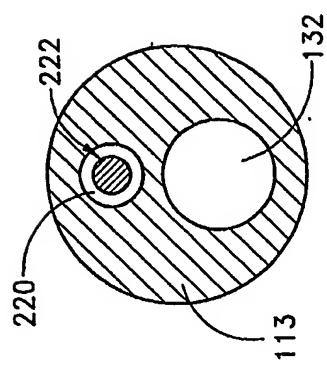


FIG. 10c

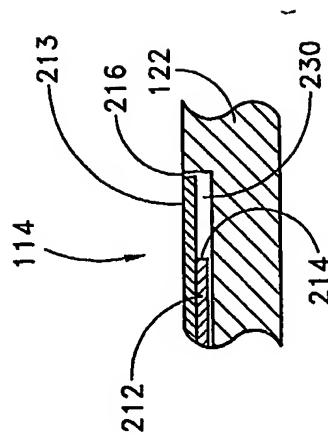
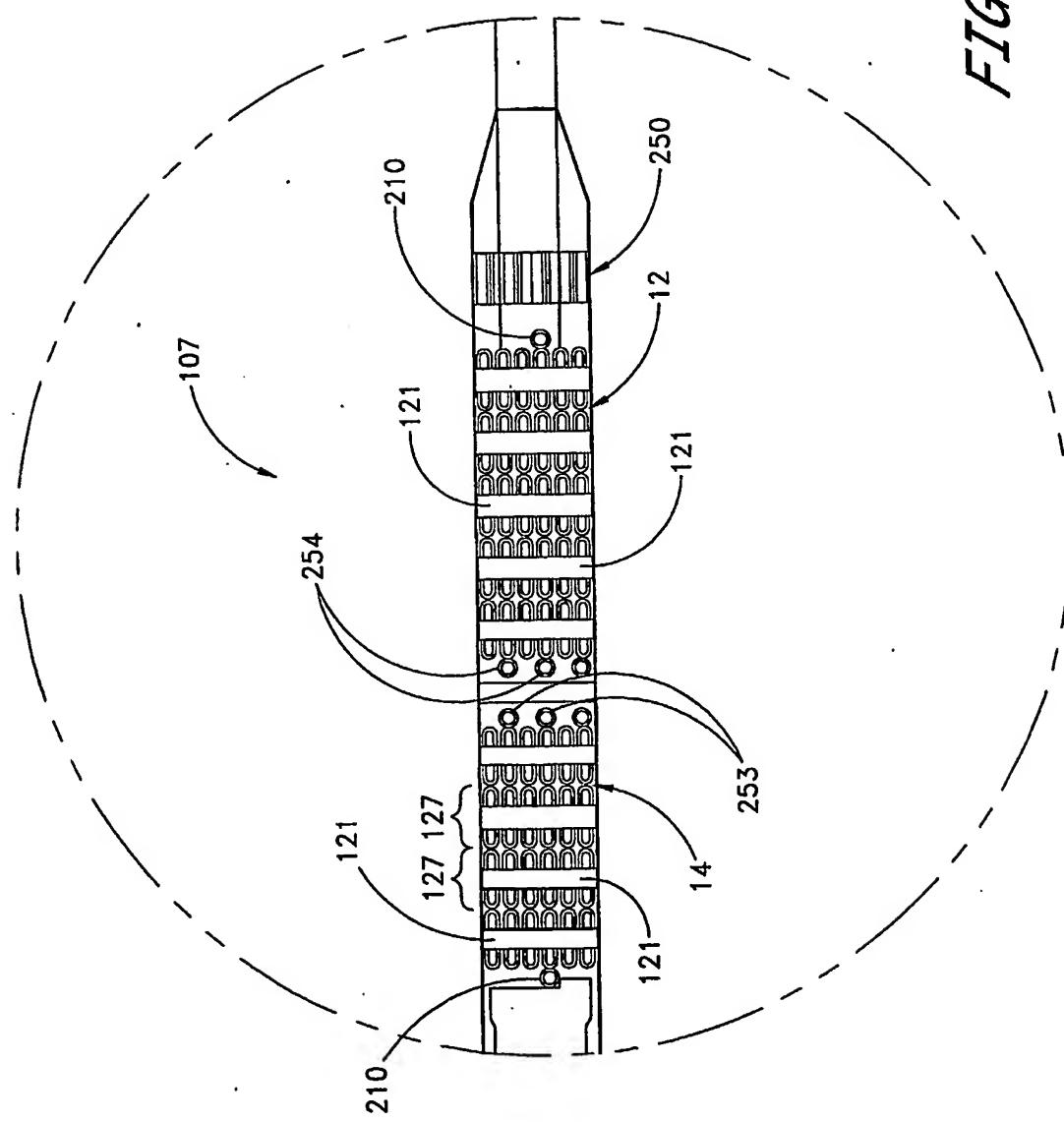


FIG. 10B

FIG. 10A



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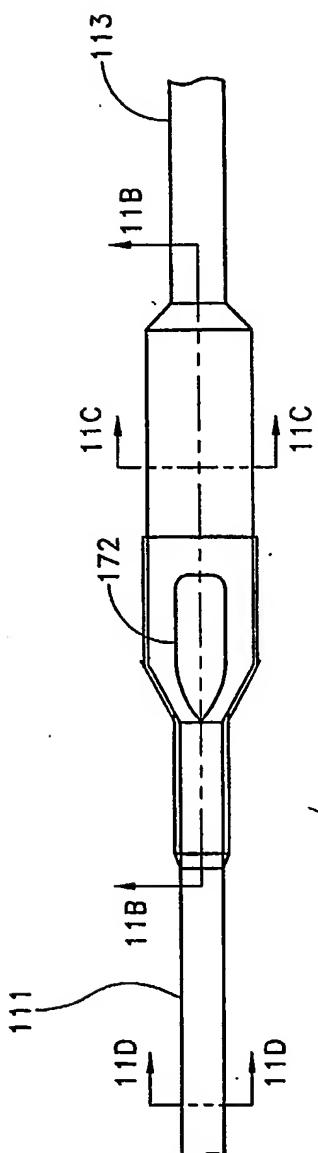


FIG. 11A



FIG. 11C

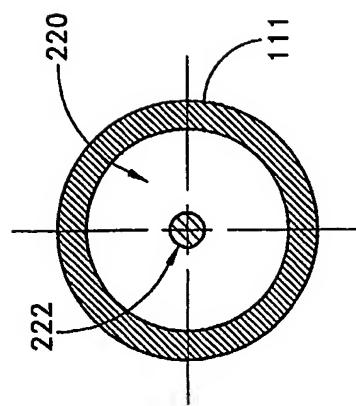


FIG. 11D

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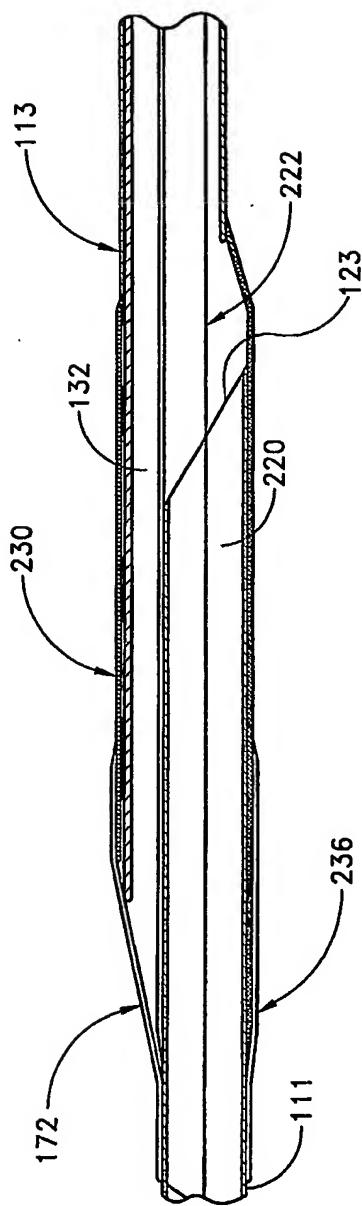


FIG. 11B

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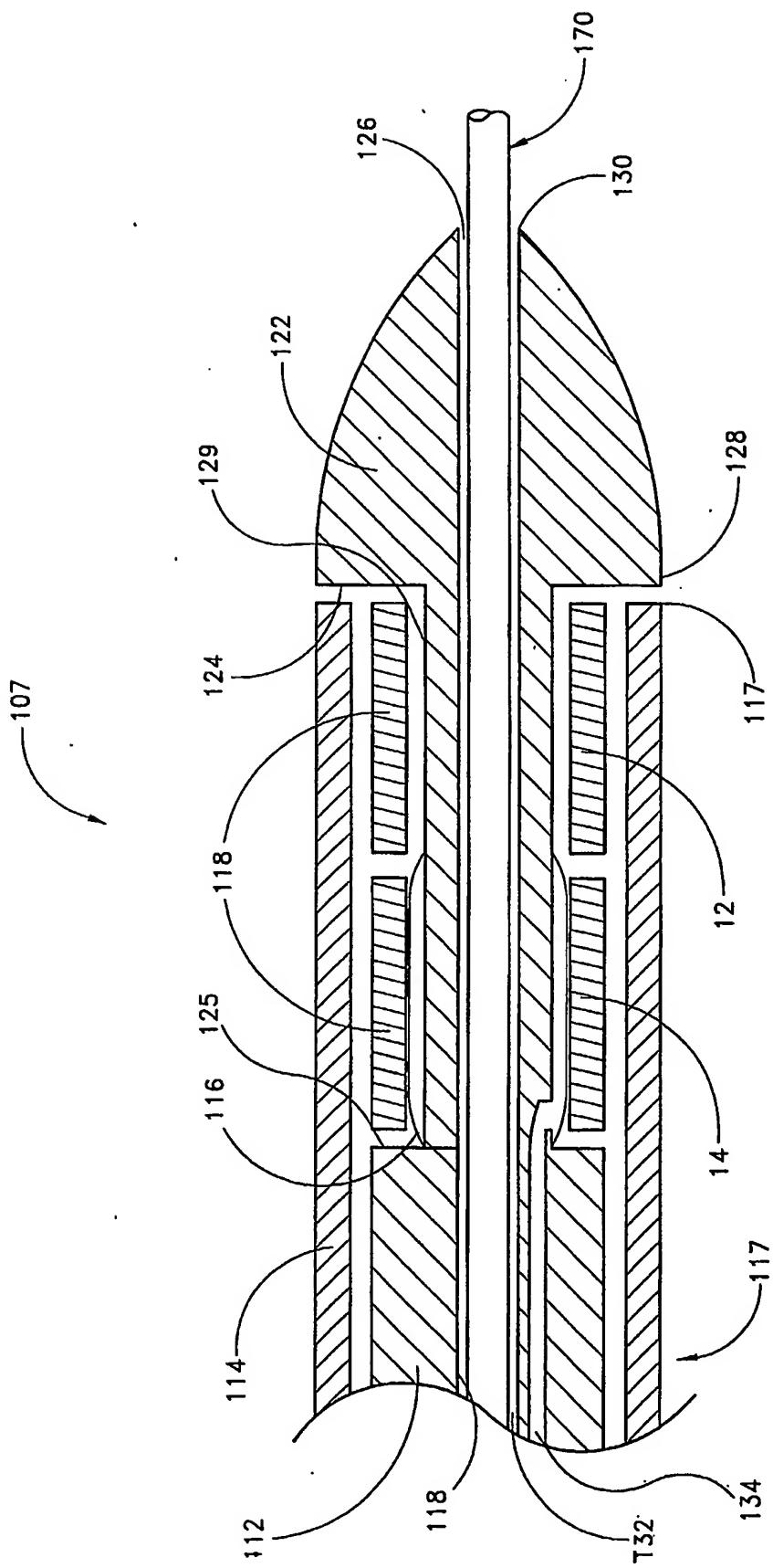


FIG. 12

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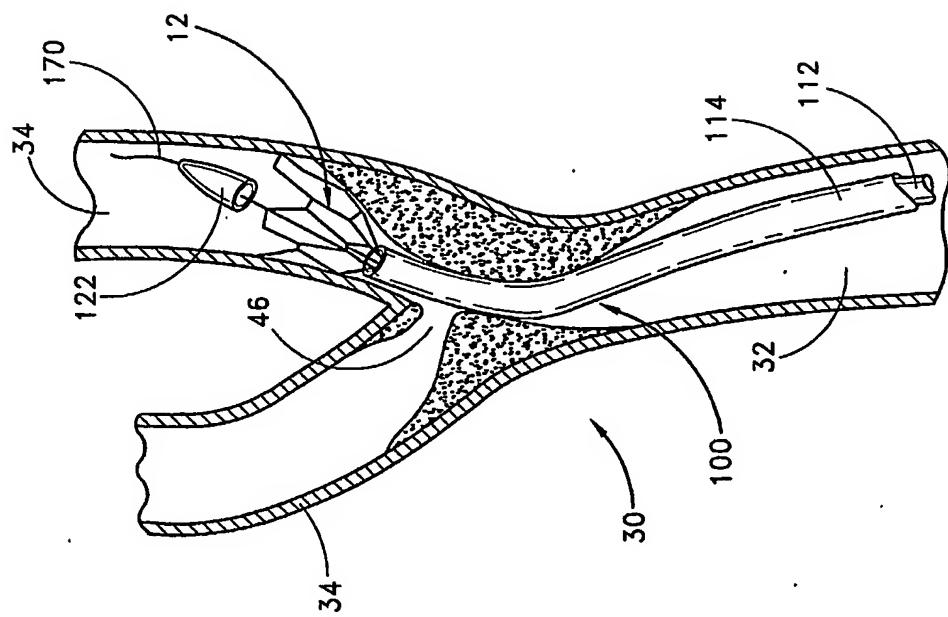


FIG. 14

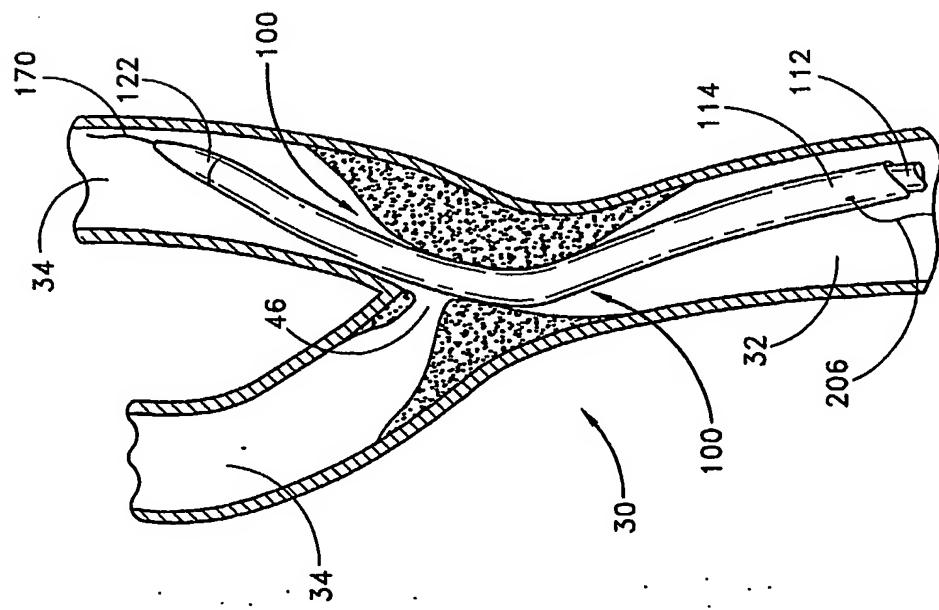


FIG. 13

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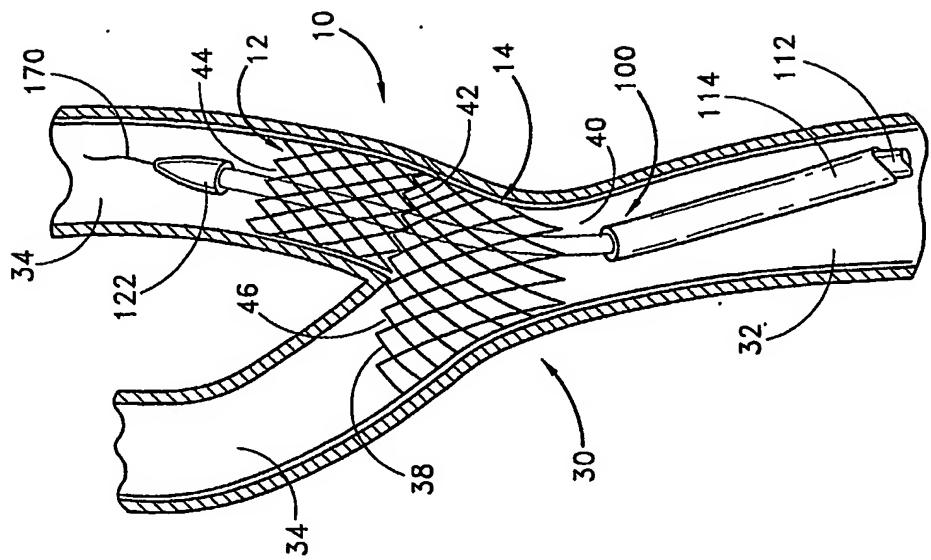


FIG. 17

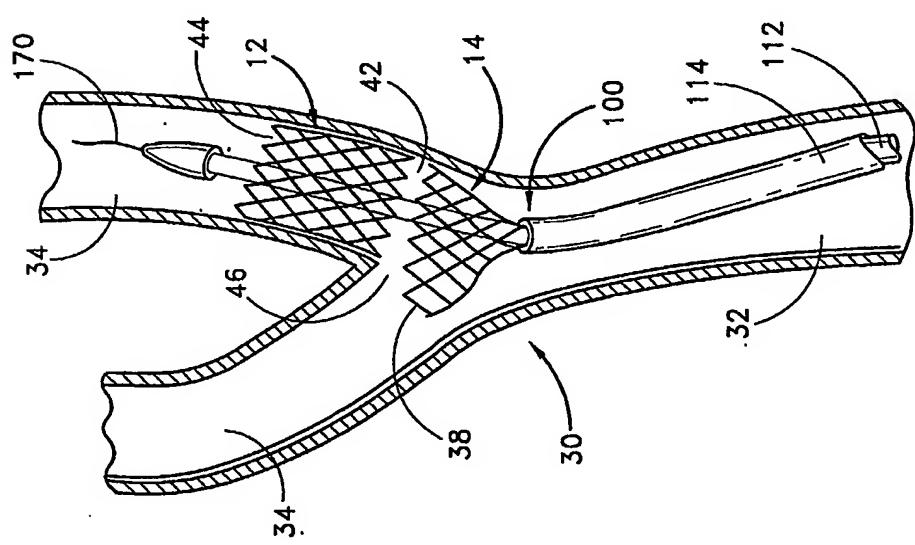


FIG. 16

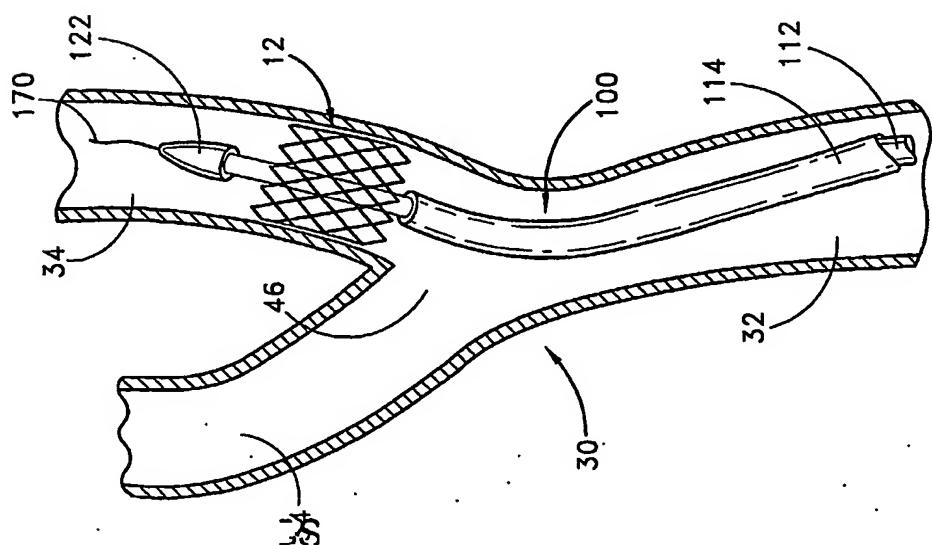


FIG. 15

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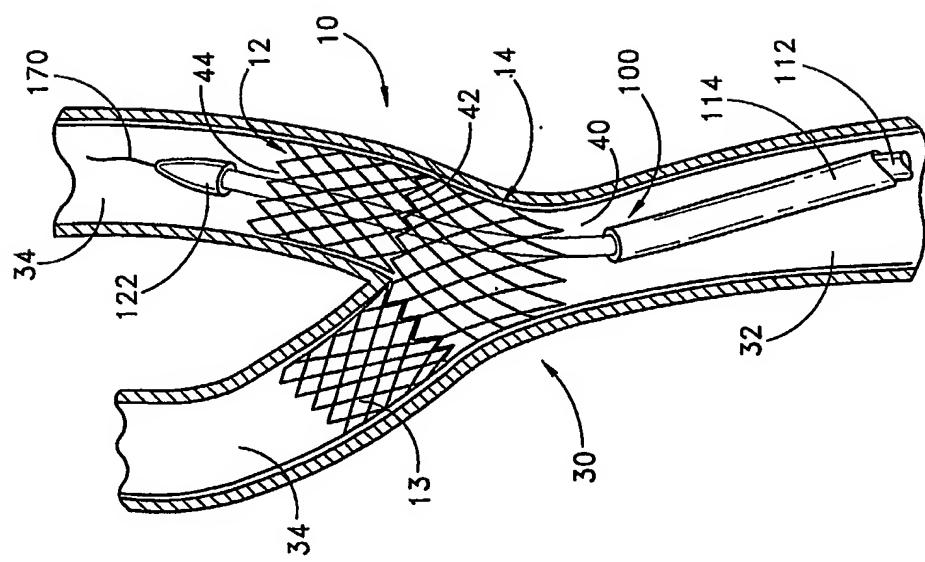


FIG. 18

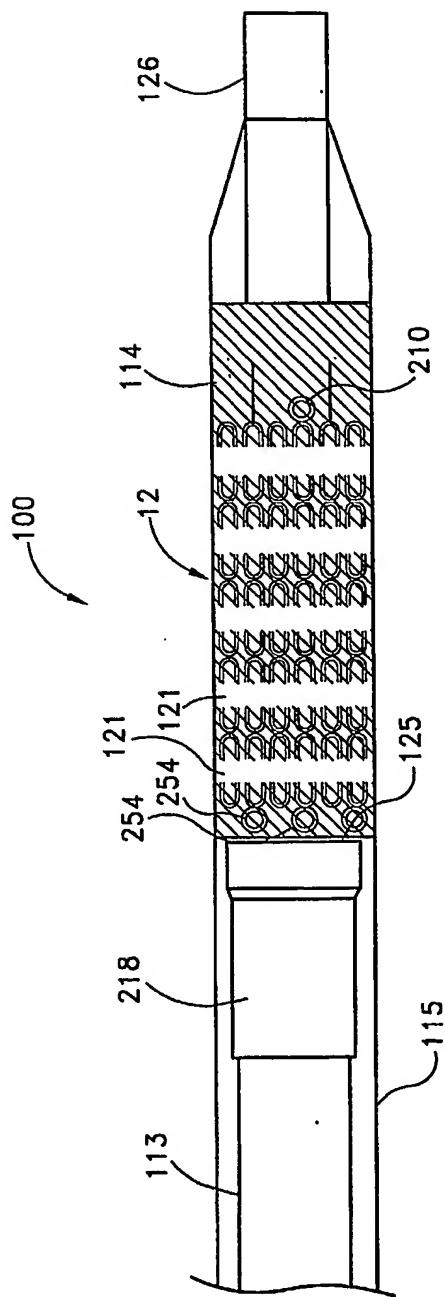


FIG. 19

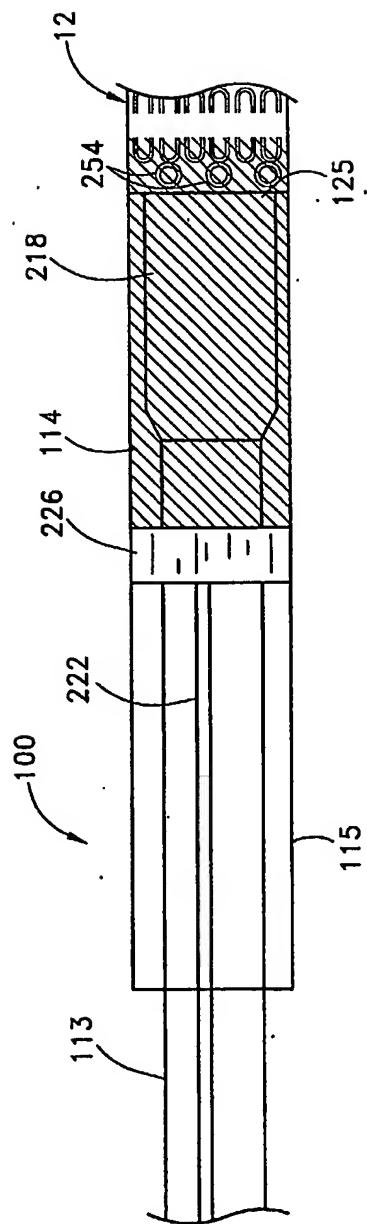


FIG. 20

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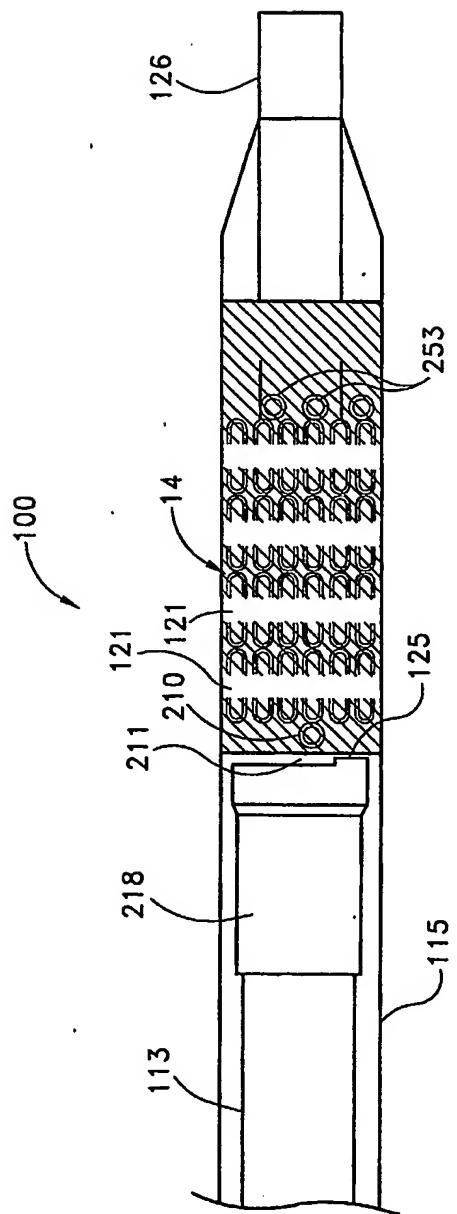


FIG. 21

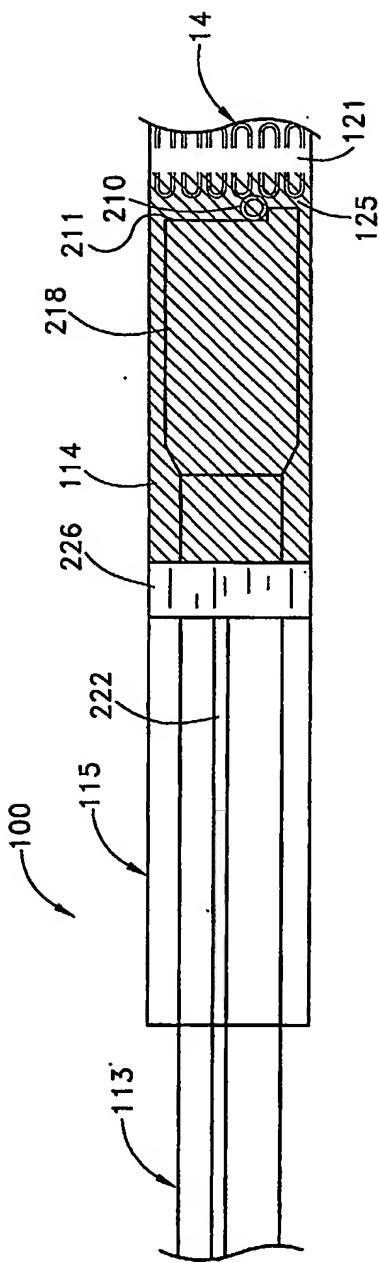


FIG. 22

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/35714

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/06
US CL : 623/1.11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/1.11, 604/264

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,676,696 A (MARCADE) 14 October 1997 (14.10.1997), See Figs. 1 and 9-10.	1,15, 13-15,18-21

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

20 February 2004 (20.02.2004)

Date of mailing of the international search report

19 APR 2004

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703)305-3230

Authorized officer

Thomas Barrett

Telephone No. 703 308 8295

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/35714

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claim Nos.: because they relate to subject matter not required to be searched by this Authority, namely: Claims 2-6, 8-9 and 12 all depend from claim 7, which is dependent upon itself. Claims 11, 16 and 17 all depend on claim 23, however there is no claim 23.
2. Claim Nos.: 2-9,11,12,16 and 17 because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claim Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.